

As confidentially submitted to the Securities and Exchange Commission on April 3, 2020.

This draft registration statement has not been filed publicly with the Securities and Exchange Commission and all information contained herein remains confidential.

Registration No. 333-

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

**FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

AXCELLA HEALTH INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or
organization)

2836
(Primary Standard Industrial
Classification Code Number)

26-3321056
(I.R.S. Employer
Identification Number)

**840 Memorial Drive
Cambridge, MA 02139
(857) 320-2200**

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

**William Hinshaw
Chief Executive Officer
840 Memorial Drive
Cambridge, MA 02139
(857) 320-2200**

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

Copies of all communications, including communications sent to agent for service, should be sent to:

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

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, 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, 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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer o	Accelerated Filer o	Non-Accelerated Filer ☒	Smaller Reporting Company ☒
			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 to Section 7(a)(2)(B) of the Securities Act. o

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 this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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 these securities nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED APRIL 3, 2020

PRELIMINARY PROSPECTUS

Shares



Axcella Health Inc.

Common Stock

We are offering _____ shares of our common stock. Our common stock is listed on the Nasdaq Global Market under the symbol "AXLA." On _____, 2020, the last reported sale price of our common stock as reported on the Nasdaq Global Market was \$ _____ per share. The final public offering price will be determined through negotiation between us and the lead underwriters in the offering and the recent market price used throughout the prospectus may not be indicative of the actual offering price.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 13 of this prospectus and under similar headings in documents incorporated by reference into this prospectus.

We are an "emerging growth company" as defined under U.S. federal securities laws and will be subject to reduced public company reporting requirements. See "Prospectus Summary—Implications of being an emerging growth company."

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

	Per Share	Total
Public Offering Price	\$	\$
Underwriting Discounts and Commissions(1)	\$	\$
Proceeds, before expenses, to us	\$	\$

(1) See "Underwriting" beginning on page 34 of this prospectus for additional information regarding total underwriter compensation.

We have granted the underwriters an option for a period of up to 30 days to purchase up to _____ additional shares of our common stock.

Delivery of the shares of common stock is expected to be made on or about _____, 2020.

J.P. MORGAN

SVB LEERINK

Prospectus dated _____, 2020

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We 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 we have prepared. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may provide you. We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the common stock.

For investors outside the United States: Neither we nor the underwriters have 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 shares of common stock and the distribution of this prospectus outside the United States.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related footnotes and the other documents incorporated by reference herein. As used in this prospectus, unless the context otherwise requires, references to the "company," "we," "us" and "our" refer to Axcella Health Inc. together with its consolidated subsidiaries.

In this prospectus, we use the following defined terms:

"product candidate" to refer to one of our investigational product candidates.

"development platform" to refer to our proprietary human-focused development platform.

"dose" to refer to the exposure amount of a product candidate in Clinical Trials and Clinical Studies.

"non-drug" to refer to a non-therapeutic use of a product candidate. Such use may be as a food product or dietary supplement.

"Clinical Trial" to refer to a human clinical study of a drug product candidate subject to the requirements for an effective Investigational New Drug application, or an IND.

"Clinical Study" to refer to Institutional Review Board-Approved, or IRB-Approved, clinical studies conducted in humans with our product candidates under U.S. Food and Drug Administration, or the FDA, regulations and guidance supporting research with food outside of an IND (prior to any decision to develop a product candidate as a drug product candidate under an IND or a non-drug product candidate). In these food studies, based on our understanding of FDA regulations and guidance, we evaluate in humans, including individuals with disease, a product candidate for safety, tolerability and effects on the normal structures and functions of the body. These studies are not designed or intended to evaluate a product candidate's ability to diagnose, cure, mitigate, treat or prevent a disease as these would be evaluated in Clinical Trials if we decide to develop a product candidate as a drug or therapeutic.

Overview

We are a clinical-stage biotechnology company focused on leveraging endogenous metabolic modulators, or EMMs, to pioneer a new approach for treating complex diseases and improving health. Our product candidates are comprised of multiple EMMs that are engineered in distinct combinations and ratios with the goal of simultaneously impacting multiple biological pathways. Our pipeline includes lead therapeutic candidates for non-alcoholic steatohepatitis, or NASH, and the reduction in risk of overt hepatic encephalopathy, or OHE, recurrence. Additional muscle- and blood-related programs are in earlier-stage development.

Using our development platform, we have efficiently designed a pipeline of product candidates that are comprised of amino acids and their derivatives, which have a general history of safe use. These orally administered compositions are designed to have the potential for multifactorial effects.

Once we design a product candidate, we decide whether to initially evaluate it in (i) a non-investigational new drug application, or non-IND, Institutional Review Board, or IRB, approved Clinical Study under U.S. Food and Drug Administration, or the FDA, regulations and guidance supporting research with food (as noted herein, the term food also includes dietary supplements) or (ii) in a Clinical Trial under an IND. A Clinical Study allows us to evaluate a product candidate's safety, tolerability and permissible secondary endpoints (e.g. impact on normal structures and functions of the body, including metabolic pathways), before we determine the next steps in its development. Our Clinical Studies are conducted at reputable medical centers following Good Clinical Practices, or GCPs, including IRB approval and monitoring, by qualified investigators, including key opinion leaders in their fields. Subsequent development options for a product candidate we initially investigate in a

Clinical Study include, but are not limited to, conducting future research in a Clinical Trial for an identified therapeutic indication, continuing research in another Clinical Study, out-licensing the product candidate, or terminating development.

In 2018, we completed three Clinical Studies. In all three studies, our product candidates were found to be generally well tolerated, and we generated structure and function biomarker data suggesting clinically relevant changes in liver and muscle metabolic pathways. We believe our ability to generate these human data at an early stage of development via initial Clinical Studies (i) significantly reduces the translational uncertainty typically seen when transitioning from animal studies to human studies, (ii) enables us to make high-insight, capital-efficient product candidate development decisions and (iii) for product candidates we initially research in Clinical Studies and subsequently decide to investigate for potential therapeutic indications, potentially increases their probability of Clinical Trial success.

We currently have three Clinical Studies underway:

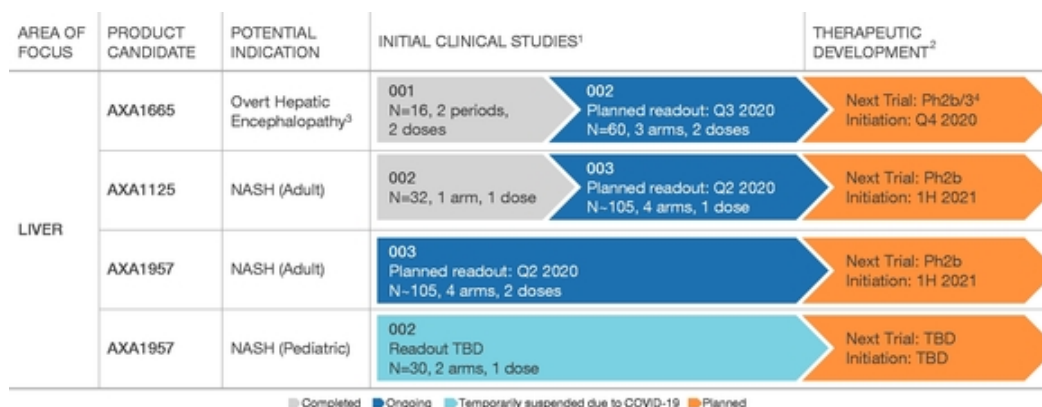
- AXA1665-002: A placebo-controlled, randomized, parallel-arm study assessing the impact of two doses of AXA1665 on safety, tolerability and structure/function secondary endpoints in approximately 60 subjects with mild and moderate hepatic insufficiency;
- AXA1125-003: A placebo-controlled, randomized, parallel-arm study assessing the impact of AXA1125 and two doses of AXA1957 on safety, tolerability and structure/function secondary endpoints in approximately 105 adult subjects with non-alcoholic fatty liver disease, or NAFLD; and
- AXA4010-001: A sequential and staged cohort study assessing the impact of AXA4010 on safety, tolerability and blood structure/function secondary endpoints in approximately 24 subjects (up to 16 adults and eight adolescents) with sickle cell disease.

In March 2020, as a result of resource reallocations at clinical sites from clinical studies and trials toward COVID-19 detection and treatment, enrollment and dosing in our AXA1957-002 pediatric Clinical Study was temporarily suspended. AXA1957-002 is a placebo-controlled, randomized, parallel-arm Clinical Study assessing the impact of one dose of AXA1957 on safety, tolerability and structure/function secondary endpoints in approximately 30 adolescent subjects with fatty liver.

Based in part on our Clinical Study results to date, along with other relevant information, in 2019, we decided to pursue future development for AXA1665 and AXA1125/AXA1957 in Clinical Trials to study their potential to modulate key pathogenic pathways associated with OHE and NASH, subject to data readouts from ongoing Clinical Studies and FDA allowance of INDs. As a result, in 2019 we declared AXA1665, AXA1125 and AXA1957 as our first therapeutic product candidates. We have yet to make a development decision for our other product candidates, AXA2678 and AXA4010.

On March 6, 2019, we had a face-to-face pre-IND meeting with the FDA for AXA1665 during which we discussed clinical endpoints, assessment tools and other matters relating to a potential IND-opening Clinical Trial for AXA1665 in patients with the complications of cirrhosis, including hepatic encephalopathy, or HE, and sarcopenia or muscle wasting in cirrhosis. Based on FDA comments received at this meeting, we believe that additional toxicology work would not be required prior to commencing a Clinical Trial for AXA1665. Assuming supportive data from our ongoing Clinical Study of AXA1665 and subject to FDA feedback and authorization to proceed under an IND, we plan to initiate a potentially registrational Phase 2b/3 Clinical Trial in the fourth quarter of 2020. We anticipate interacting with the FDA again in 2020 prior to a formal IND submission for AXA1665.

An overview of these product candidates and their development status is illustrated below.



- (1) Initial Clinical Studies refers to Non-IND Clinical Studies initiated prior to a development path decision.
- (2) Planned Clinical Trial, contingent upon final data readouts from ongoing Clinical Studies and allowance by the FDA.
- (3) Indication expected to be reduction in risk of overt hepatic encephalopathy recurrence.
- (4) We believe that this has the potential to serve as a registrational Clinical Trial, contingent upon final data readout from ongoing Clinical Study and allowance by the FDA.

We have yet to make a development decision for our other product candidates, AXA2678 and AXA4010.

About Endogenous Metabolic Modulators (EMMs)

EMMs encompass a broad set of molecular families, including amino acids, bile acids other intermediary substrates and hormones. Together, these molecules can serve as master regulators and signaling agents, driving multiple pathways to elicit multifactorial effects that integrate basic cellular functioning to impact fundamental biologies. Such biologies include cellular bioenergetics (e.g., tricarboxylic acid cycle and electron transport chain), nutrient handling (e.g., de novo lipogenesis, or metabolic formation of fat, gluconeogenesis, or the generation of glucose from certain non-carbohydrate carbon substrates, and proteogenesis, or protein formation), nutrient sensing via master regulators (e.g., via mammalian target of rapamycin, or mTOR, 5' AMP-activated protein kinase, or AMPK, fibroblast growth factor 21, or FGF21, and peroxisome proliferator-activated receptors, or PPARs), immune response and inflammation, reactive oxygen response, vascular function, neurotransmitter signaling, tissue repair, and autophagy.

Our EMM Composition Design and Nonclinical Research Approach

Design Approach

Our development platform allows us to efficiently design and test EMM compositions that simultaneously target multiple biologies and metabolic pathways. This platform integrates advanced analytics of metabolic regulation and dysregulation to interrogate data in our proprietary databases, which we refer to as Xcella Database, or XcellaDB, and Xcella Knowledge Base, or XcellaKB. Our human primary cell systems also directly test the multiple biologies that are particularly disease-related and/or drive metabolic dysregulation. All of this is supported by what we believe to be the world's leading EMM safety database. The data and learnings generated through this process further inform our design methodology, increasing our development platform's efficiency for the development of subsequent product candidates.

AxcellaDB, our proprietary database, synthesizes a combination of data from published scientific and medical literature, our in vitro models, and our human Clinical Studies. Through advanced analytics, we investigate novel, causal connections among EMMs, biology, health and/or disease. We believe this enables us to take a systems biology approach to product candidate discovery and development. Ultimately, we envision utilizing AxcellaKB and its internal machine learning capabilities to identify EMM compositions, predict their effects on biology and potentially identify new target areas for our platform.

Nonclinical Research

We test EMM compositions and hypothesized synergies in normal and disease-specific human primary cell models. We conduct our model systems in environments that aim to simulate physiological levels of biofluids and nutrients. These models include multiple cell types that we use to deconstruct dysregulated metabolism or disease conditions to isolate effects of EMM compositions on subsets of metabolic pathways. The throughput of these models enables us to test product candidates as well as combinations of the individual constituents to identify and better understand their interactions.

Pharmacokinetic, or PK, literature, experiments and modeling inform our EMM compositions (i.e. amounts and ratios). We are able to evaluate EMM plasma exposure, supra-physiological exposures, windows of exposure administration amounts, the characterization of critical PK behaviors across molecule classes, and the implications of physiological compartmental distribution. We believe these data can be used to refine product candidate designs.

Our Clinical Approach and Development Path Decision Making

Once a product candidate is designed, we then decide whether to evaluate the candidate in a Clinical Study or under a Clinical Trial. To date, we have initially conducted clinical investigations of our product candidates in Clinical Studies. Going forward, we may conduct initial clinical investigations of future product candidates under Clinical Trials.

We conduct our Clinical Studies under the FDA's September 2013 Guidance for Clinical Investigators, Sponsors, and IRBs entitled "Investigational New Drug Applications (INDs)—Determining Whether Human Research Studies Can Be Conducted Without an IND," which we believe allows for Clinical Studies to be conducted to assess a food product's safety, tolerability and effect on normal structures or functions in humans in healthy and diseased subjects. Our current product candidates comprise amino acids and their derivatives. We select the amounts of the amino acids and derivatives used in our product candidates based upon doses previously found in third-party clinical studies and third-party clinical trials to be tolerable with no significant safety concerns. Therefore, we believe we can study our product candidates in Clinical Studies as food and dietary supplements.

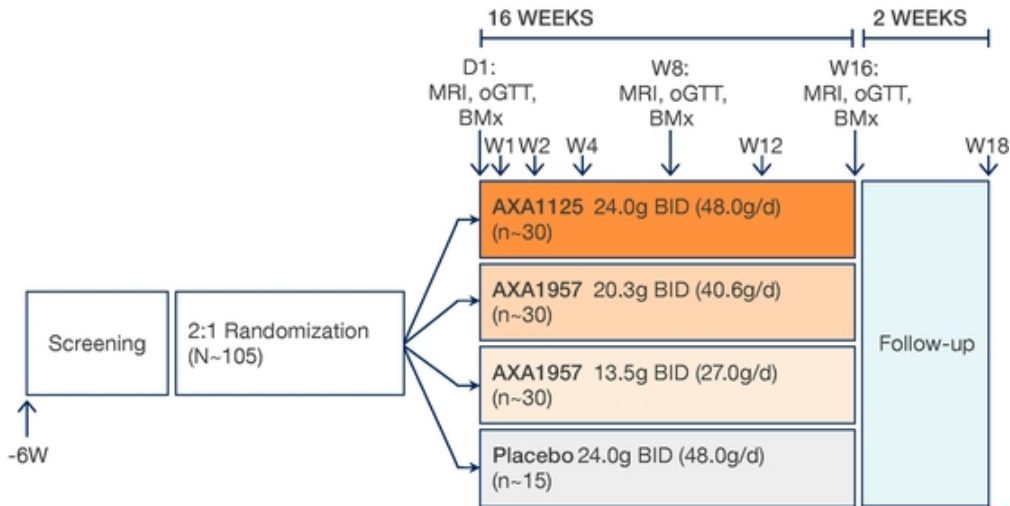
Our Clinical Studies include an assessment of safety and tolerability and a substantial number of biomarkers that may inform biologies relevant to the healthy structures and functions of the body but are not designed or intended to evaluate a product candidate's ability to diagnose, cure, mitigate, treat or prevent a disease or other health condition. They are conducted at reputable medical centers following GCPs, including IRB approval and monitoring, by qualified investigators, including key opinion leaders in their fields. Using a combination of data from these Clinical Studies and/or other relevant information, we decide whether to advance the product candidate's development in a therapeutic path under a Clinical Trial, further research the product candidate in another Clinical Study, out-license commercialization rights to the product candidate, or terminate its development. We may decide to partner with other companies in the development or commercialization of our product candidates.

In 2019, we determined that our lead compounds, AXA1665, AXA1125 and AXA1957, will be pursued as therapeutic product candidates, meaning that any future assessment of these product candidates will be made in Clinical Trials, subject to final data readouts from ongoing Clinical Studies and FDA allowance of INDs. These Clinical Trials would therefore be designed to evaluate each product candidate's ability to diagnose, cure, mitigate, treat or prevent targeted diseases (OHE for AXA1665 and NASH for AXA1125 and AXA1957).

Recent developments

Clinical Study AXA1125-003

AXA1125-003 is an ongoing 16-week (with a two-week follow-up), randomized, single-blind, placebo-controlled, Clinical Study to assess safety, tolerability and impact on the liver structure and function of AXA1125 and AXA1957 in approximately 105 adult subjects with NAFLD. Key inclusion criteria for this study included having at least 10% fat by MRI-PDFF and a corrected T1, or cT1, a measure of liver injury by multiparametric MRI, of at least 830 mSec. Randomization was stratified by the presence or absence of T2D. In this study, subjects receive either AXA1125, two different doses of AXA1957 or a calorie-matched placebo control twice a day, or BID (see figure below). Enrollment of 102 subjects in this study was completed in late 2019.

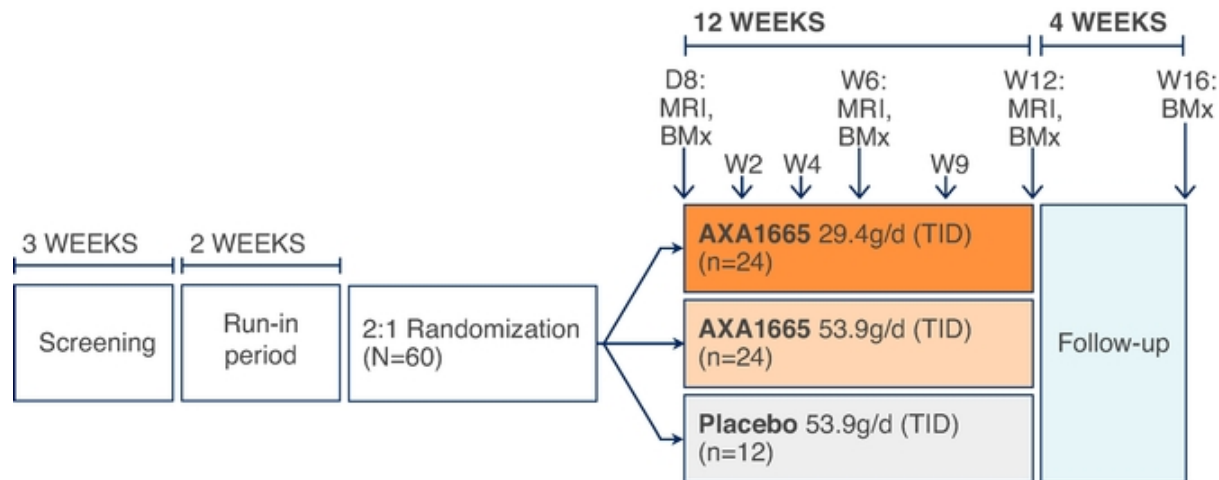


Study design for AXA1125-003. This Clinical Study was initiated prior to determination of AXA1125 and AXA1957 as therapeutic product candidates.

Completion of enrollment in this study was announced in October 2019. In January 2020, we announced positive interim findings from this ongoing study. This interim analysis included data from approximately half of the study population through the full 16 weeks of administration. The analysis showed that AXA1125 and both doses of AXA1957 had been generally well tolerated as of the date of the interim analysis. Additionally, both AXA1125 and AXA1957 data suggested clinically relevant responses and directional changes on the three biological nodes: metabolism (MRI-PDFF and HOMA-IR), inflammation (ALT, CK-18, cT1) and fibrogenesis (proC3). The onset of response in some biomarkers was seen as early as the eight-week post-baseline assessment with continued improvement through 16 weeks. We anticipate reporting top-line data from this study in the second quarter of 2020. We do not currently anticipate the COVID-19 outbreak to impact the timing of this readout.

Clinical Study AXA1665-002

AXA1665-002 is an ongoing 12-week (with a four-week follow-up) randomized, placebo-controlled Clinical Study to assess AXA1665's safety, tolerability and impact on normal liver and muscle structures and functions in approximately 60 adult subjects with mild (Child A) and moderate (Child B) hepatic insufficiency.



Study design for AXA1665-002. This Clinical Study was initiated prior to determination of AXA1665 as a therapeutic product candidate.

The assessments in AXA1665-002 include:

Primary Safety & tolerability	Clinical AEs, vital signs, ECGs, clinical laboratory parameters, including standard chemistry and hematology panels, plasma ammonia, albumin, total protein and other liver function tests
Secondary PK of AXA1665 constituents and endogenous amino acid levels	FR* and VPR*
Physiological assessments	Normal Structure <ul style="list-style-type: none">Body composition via MRI to assess lean and fat mass compartments, including thigh muscle volumes, intramuscular fat Normal Function <ul style="list-style-type: none">Physical (LFI*; gait speed)Cognitive (Stroop test; PHES; CFF)Health-related questionnaires

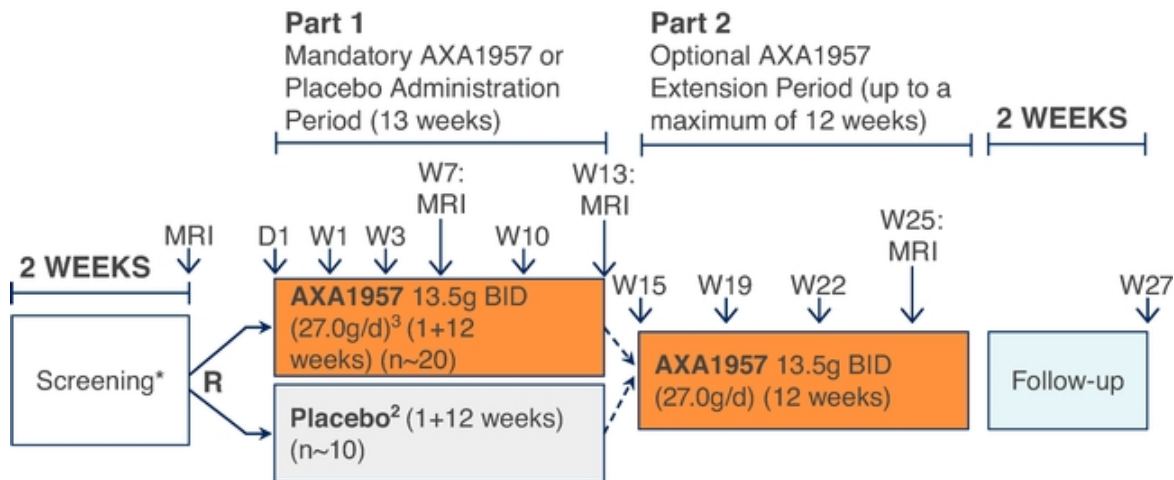
* FR, VPR and LFI are believed to have prognostic significance in subjects with cirrhosis and end-stage liver disease based on emerging scientific literature. PHES = psychometric hepatic encephalopathy score; CFF = critical flicker frequency.

Enrollment in AXA1665-002 was completed in February 2020, and AXA1665 continued to be generally well tolerated through week 12. Top-line data from this Clinical Study is anticipated in the third quarter of 2020. We do not currently anticipate the COVID-19 outbreak to impact the timing of this readout.

Clinical Study AXA1957-002

AXA1957-002 is a placebo-controlled, single-blind, randomized (2:1) controlled Clinical Study to assess safety and tolerability and the impact of AXA1957 on the normal structures and functions of the liver in approximately 30 adolescent (12-17 year old) subjects with NAFLD. Key inclusion criteria include at least 10% liver fat by MRI-PDFF and a cT1 of > 820 mSec. Subjects are stratified by the presence or absence of T2D. This is among the few clinical programs undertaken to date in a population of adolescent subjects with NAFLD.

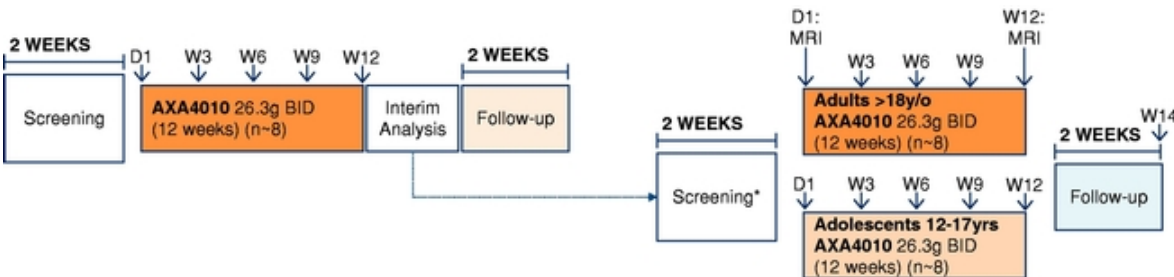
As a result of resource reallocations at clinical sites involved in AXA1957-002 from clinical studies and trials toward COVID-19 detection and treatment, enrollment and dosing in this Clinical Study was temporarily suspended in March 2020. We continue to view pediatric NASH as a significant area of unmet need and, utilizing the information gathered thus far from AXA1957-002 and the expected top-line data readout from AXA1125-003, we expect to provide an update on our plans for this program at a future date.



Study design for AXA1957-002. This Clinical Study was initiated prior to determination of AXA1125 and AXA1957 as therapeutic product candidates.

Clinical Study AXA4010-001

AXA4010-001 is an ongoing Clinical Study that is expected to enroll up to 24 subjects ages 12 and older in a staged sequential design of three separate cohorts each for up to 12 weeks (see study design below).



Study design for AXA4010-001.

In addition to safety and tolerability, the study will assess the effects of AXA4010 on normal blood structure and function, including hemolysis, inflammation and vascular physiology. The first cohort will consist of eight adult subjects with sickle cell disease, or SCD, to test whether AXA4010 can impact normal blood and vascular function. Subsequently, additional adult subjects as well as adolescent subjects may be enrolled into the study. SCD is a chronic hemolytic anemia that is associated with inflammation and metabolic derangements that include nitric oxide depletion and oxidative stress. As a result, we believe SCD is an appropriate biological model in which to study AXA4010's potential impact on multiple aspects of blood health. We currently anticipate a data readout from Cohort 1 of this study in the fourth quarter of 2020.

Corporate history

We were incorporated in August 2008 under the laws of the state of Delaware under the name Newco LS16, Inc. Our name was changed to Axcella Health Inc. in June 2016. Our principal executive offices are located at 840 Memorial Drive, Cambridge, MA 02139, and our phone number is (857) 320-2200. Our website address is <https://www.axcellahealth.com>. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus.

We own various U.S. federal trademark applications and unregistered trademarks, including our company name and our logo. All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the symbols ® and ™, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

Implications of being an emerging growth company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

We will remain an emerging growth company until the earlier to occur of (1) December 31, 2024, (2) the last day of the fiscal year in which we have total annual gross revenues of at least \$1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a "large accelerated filer," under the rules of the U.S. Securities and Exchange Commission, or SEC, which means the market value of our equity securities that is held by non-affiliates exceeds \$700 million as of the prior June 30th and (4) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

In addition, 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. This provision allows an emerging growth company to delay the adoption of some accounting standards until those

standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company.

THE OFFERING

Common stock offered by us shares

Common stock to be
outstanding immediately
after this offering shares (or shares if the underwriters exercise their option to purchase additional shares in full)

Option to purchase
additional shares offered
by us shares

Use of proceeds We estimate that we will receive net proceeds from the sale of shares of our common stock in this offering of approximately \$ million, or \$ million if the underwriters exercise their option to purchase additional shares in full, assuming a public offering price of \$ per share, the last reported trading price of our common stock on the Nasdaq Global Market on , 2020, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to advance our current liver programs, including our planned IND filing for AXA1665 and ensuing initiation of Clinical Trials and our planned IND filing(s) for our NASH program (AXA1125 and/or AXA1957) in adults and in pediatric subjects and ensuing initiation of Clinical Trials; to advance our product candidate AXA4010, including our ongoing Clinical Study; to advance our development platform and discovery efforts; and to support organizational growth and for working capital and other general corporate purposes. For a more complete description of our intended use of the proceeds from this offering, see "Use of Proceeds."

Risk factors You should carefully read the "Risk Factors" section of this prospectus and under similar headings in documents incorporated by reference into this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.

Nasdaq Global Market
symbol "AXLA"

The number of shares of our common stock to be outstanding after this offering is based on 23,188,816 shares of our common stock outstanding as of December 31, 2019 and excludes:

- 5,176,944 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2019 under our 2010 Stock Incentive Plan, or our 2010 Plan, and our 2019 Stock Option and Incentive Plan, or our 2019 Plan, with a weighted-average exercise price of \$7.35 per share;
- 66,801 shares of common stock reserved for vesting of restricted stock units outstanding as of December 31, 2019 under our 2019 Plan;
- 36,466 shares of common stock available for future issuance as of December 31, 2019 under our 2019 Plan; and

- 237,181 shares of our common stock available for future issuance as of December 31, 2019 under our 2019 Employee Stock Purchase Plan, or our 2019 ESPP.

Unless otherwise indicated, all information in this prospectus reflects or assumes the following:

- no exercise of the outstanding options described above; and
- no exercise by the underwriters of their option to purchase additional shares of common stock in this offering.

SUMMARY CONSOLIDATED FINANCIAL DATA

You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section incorporated by reference from our Annual Report on Form 10-K for the year ended December 31, 2019. We have derived the consolidated statements of operations data for the years ended December 31, 2019 and 2018 and the consolidated balance sheet data as of December 31, 2019 and 2018 from our audited consolidated financial statements incorporated by reference in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future.

	Year Ended December 31,	
	2019	2018
	(in thousands, except share and per share data)	
Operating expenses:		
Research and development	\$ 41,658	\$ 25,486
General and administrative	15,781	8,410
Total operating expenses	57,439	33,896
Loss from operations	(57,439)	(33,896)
Other income (expense):		
Change in fair value of preferred stock warrant liability	(51)	(14)
Interest income (expense), net	(1,547)	(2,159)
Total other income (expense), net	(1,598)	(2,173)
Net loss	\$ (59,037)	\$ (36,069)
Net loss per share, basic and diluted(1)	\$ (3.55)	\$ (7.97)
Weighted average common shares outstanding, basic and diluted	16,624,941	4,546,373

- (1) See Note 11 to our consolidated financial statement incorporated by reference in this prospectus for details on the calculation of basic and diluted net loss per share.

	As of December 31,	
	2019	2018
	(in thousands)	
Balance Sheet Data:		
Cash and cash equivalents	\$ 92,053	\$ 79,466
Working capital(1)	85,184	73,390
Total assets	94,359	81,844
Long term debt, net of discount	24,897	24,521
Other liabilities(2)	882	1,898
Preferred stock warrant liability	—	425
Redeemable convertible preferred stock	—	197,842
Total stockholders' equity (deficit)	60,224	(149,753)

- (1) We define working capital as current assets less current liabilities.
- (2) As of December 31, 2018, this includes a \$1.2 million success fee relating to our loan and security agreement with Solar, which was paid upon the completion of our IPO in May 2019.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus and the documents incorporated by reference into this prospectus, including the risks identified under "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, before deciding whether to invest in our common stock. The occurrence of any of the events or developments described therein and below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks related to our common stock and this offering

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the net tangible book value of your shares.

The public offering price will be substantially higher than the as adjusted net tangible book value per share of our common stock after this offering. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the as adjusted net tangible book value per share after this offering. As a result, investors purchasing common stock in this offering will incur immediate dilution of \$ per share, based on an assumed public offering price of \$ per share, the last reported trading price of our common stock on the Nasdaq Global Market on , 2020, representing the difference between our as adjusted net tangible book value per share after giving effect to this offering and the assumed public offering price. To the extent outstanding stock options are exercised, new stock options are issued or we issue additional shares of common stock in the future, there will be further dilution to new investors. As a result of the dilution to investors purchasing common stock in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see "Dilution."

We have broad discretion in the use of our existing cash, cash equivalents and the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of our existing cash, cash equivalents and the net proceeds from this offering, including for any of the purposes described in the section entitled "Use of Proceeds," and you will not have the right or opportunity as part of your investment decision to assess whether such proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of our existing cash, cash equivalents and the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our existing cash, cash equivalents and the net proceeds from this offering in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Our ability to use NOLs and research and development credits to offset future taxable income may be subject to certain limitations.

As of December 31, 2019, we had U.S. federal and state net operating loss, or NOL, carryforwards of \$192.1 million and \$188.3 million, respectively. These amounts begin to expire in 2030. The federal

net operating losses generated in 2018 and 2019 can be carried forward indefinitely. As of December 31, 2019, we also had U.S. federal and state research and development tax credit carryforwards of \$6.1 million and \$2.3 million, respectively, both of which expire at various dates through 2039. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future taxable income or tax liabilities, respectively. While federal NOLs generated after December 31, 2017 will not be subject to expiration, they generally may not be carried back to prior taxable years except that, under the "Coronavirus Aid, Relief, and Economic Security Act," net operating losses generated in 2018, 2019 and 2020 may be carried back five taxable years. Additionally, for taxable years beginning after December 31, 2020, the deductibility of federal net operating losses generated in taxable years beginning after December 31, 2017 is limited to 80% of our taxable income in such year (after taking into account utilization of NOLs generated in taxable years beginning before January 1, 2018), where taxable income is determined without regard to the NOL deduction itself. In addition, in general, under Sections 382 and 383 of the Code, and corresponding provisions of state law, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOL carryforwards or tax credits, or Credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Our existing NOLs or Credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with this offering, our ability to utilize NOLs or Credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. If finalized, Treasury Regulations currently proposed under Section 382 of the Code may further limit our ability to utilize our pre-change NOL carryforwards or Credits if we undergo a future ownership change. Our NOLs or Credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or Credits. Furthermore, our ability to utilize our NOLs or Credits is conditioned upon our attaining profitability and generating U. S. federal and state taxable income. We have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOLs or Credits.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into this prospectus contain forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this prospectus and the documents incorporated by reference into this prospectus are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expects", "intends", "plans", "anticipates", "believes", "estimates", "predicts", "potential", "continue" or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the initiation, success, cost and timing of our product development activities, preclinical studies, Clinical Studies and Clinical Trials, including statements regarding the timing of initiation and completion of preclinical studies, Clinical Studies or Clinical Trials and related preparatory work, and the timing of the availability of the results of these preclinical studies, Clinical Studies and Clinical Trials;
- our ability to obtain funding for our operations, including funding necessary to complete further development of our initial product candidates, and if successful, commercialization of these candidates as drug or non-drug products;
- the potential for our identified research priorities to advance our development platform, development programs or product candidates;
- our ability to obtain and maintain regulatory approval or find alternate regulatory commercialization pathways from the FDA, the European Medicines Agency, or the EMA, and other comparable regulatory authorities for our product candidates, and any related restrictions, limitations or warnings in the label of an approved product candidate;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates, development platform and the type of such protection;
- our ability and the potential to successfully manufacture our product candidates for preclinical studies, Clinical Studies and Clinical Trials and for commercial use, if approved;
- the size and growth potential of the markets for our product candidates and our ability to serve those markets, either alone or in combination with others;
- the rate and degree of market acceptance of our product candidates, if approved;
- regulatory developments in the United States and foreign countries;
- our ability to enter into a collaboration, partnership, or other agreement with a third party on reasonable terms or at all to develop one or more product candidates or commercialize any of our product candidates, if approved;
- our ability to secure sufficient manufacturing and supply chain capacity;
- the success of competing products or therapies that are or may become available;
- our ability to attract and retain key scientific, management or other necessary personnel;
- our estimates regarding expenses for both product development and as a public company, future revenue, capital requirements and needs for additional financing;
- the potential for faults in our internal controls;
- the effect of the COVID-19 outbreak on any of the foregoing; and

- other risks and uncertainties, including those discussed in "Risk Factors" and "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, which is incorporated by reference into this prospectus.

Any forward-looking statements in this prospectus and the documents incorporated by reference into this prospectus reflect our current views with respect to future events and with respect to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under "Risk Factors" and "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, which is incorporated by reference into this prospectus, and elsewhere in this prospectus and the documents incorporated by reference into this prospectus. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this prospectus and the documents incorporated by reference into this prospectus. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

USE OF PROCEEDS

We estimate that we will receive net proceeds from the sale of shares of our common stock in this offering of approximately \$ million, or \$ million if the underwriters exercise their option to purchase additional shares in full, assuming a public offering price of \$ per share, the last reported trading price of our common stock on the Nasdaq Global Market on , 2020, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A \$1.00 increase (decrease) in the assumed public offering price of \$ per share, the last reported trading price of our common stock on the Nasdaq Global Market on , 2020, would increase (decrease) the net proceeds to us from this offering by approximately \$ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Similarly, an increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering by approximately \$ million, assuming that the assumed public offering price remains the same. We do not expect that a change in the public offering price or the number of shares by these amounts would have a material effect on our uses of the proceeds from this offering, although it may accelerate the time at which we will need to seek additional capital.

We currently expect to use the net proceeds from this offering, together with our cash and cash equivalents as of December 31, 2019, to advance our current liver programs, including our planned IND filing for AXA1665 and ensuing initiation of Clinical Trials and our planned IND filing(s) for our NASH program (AXA1125 and/or AXA1957) in adults and in pediatric subjects and ensuing initiation of Clinical Trials; to advance our product candidate AXA4010, including our ongoing Clinical Study; to advance our development platform and discovery efforts; and to support organizational growth and for working capital and other general corporate purposes.

As of December 31, 2019, we had \$92.1 million of cash and cash equivalents on hand. Based on our current plans, we believe our cash and cash equivalents as of December 31, 2019, together with the net proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements through . We have based these estimates on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances, or a combination of one or more of these sources.

We cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. Due to uncertainties inherent in the development process, it is difficult to estimate the exact amounts of the net proceeds that will be used for any particular purpose. We may use our existing cash, cash equivalents and the future payments, if any, generated from any future collaboration agreements to fund our operations, either of which may alter the amount of net proceeds used for a particular purpose. In addition, the amount, allocation and timing of our actual expenditures will depend upon numerous factors, including the results of our research and development efforts, the timing and success of our Clinical Studies and Clinical Trials and the timing of regulatory submissions. Accordingly, we will have broad discretion in using these proceeds.

Pending their uses, we plan to invest the net proceeds of this offering in short-term, interest-bearing, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of December 31, 2019:

- on an actual basis; and
- on an as adjusted basis to give effect to our issuance and sale of shares of our common stock in this offering at the assumed public offering price of \$ per share, the last reported trading price of our common stock on the Nasdaq Global Market on , 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information in this table together with our consolidated financial statements and the related notes incorporated by reference in this prospectus and the "Summary Consolidated Financial Data" section of this prospectus.

	As of December 31, 2019	
	Actual	As Adjusted
	(in thousands, except share and per share data)	
Cash and cash equivalents	\$ 92,053	\$
Long term debt, net of discount	24,897	24,897
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized and no shares issued or outstanding, actual and as adjusted	—	—
Common stock, \$0.001 par value; 150,000,000 shares authorized, actual and as adjusted; 23,607,797 shares issued and 23,188,816 shares outstanding, actual; shares issued and shares outstanding, as adjusted	24	
Additional paid-in capital	276,286	
Treasury stock, 418,981 shares at cost	—	
Accumulated deficit	(216,086)	
Total stockholders' equity (deficit)	(60,224)	
Total capitalization	\$ (35,327)	\$

A \$1.00 increase (decrease) in the assumed public offering price of \$ per share, the last reported trading price of our common stock on the Nasdaq Global Market on , 2020, would increase (decrease) the as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by \$ million, assuming no change in the assumed public offering price per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The table above does not include:

- 5,176,944 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2019 under our 2010 Plan and our 2019 Plan, with a weighted-average exercise price of \$7.35 per share;
- 66,801 shares of common stock reserved for vesting of restricted stock units outstanding as of December 31, 2019 under our 2019 Plan;
- 36,466 shares of common stock available for future issuance as of December 31, 2019 under our 2019 Plan; and
- 237,181 shares of our common stock available for future issuance as of December 31, 2019 under our 2019 ESPP.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value (deficit) as of December 31, 2019 was \$60.2 million, or \$2.60 per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities. Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the 23,188,816 shares of our common stock outstanding as December 31, 2019.

After giving effect to our issuance and sale of _____ shares of our common stock in this offering at the assumed public offering price of \$ _____ per share, the last reported trading price of our common stock on the Nasdaq Global Market on _____, 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of December 31, 2019 would have been \$ _____ million, or \$ _____ per share. This represents an immediate increase in as adjusted net tangible book value per share of \$ _____ to existing stockholders and immediate dilution of \$ _____ in as adjusted net tangible book value per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting as adjusted net tangible book value per share after this offering from the public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed public offering price per share	\$ _____
Historical net tangible book value (deficit) per share as of December 31, 2019	\$ 2.60
Increase in as adjusted net tangible book value per share attributable to new investors purchasing common stock in this offering	_____
As adjusted net tangible book value per share after this offering	_____
Dilution per share to new investors purchasing common stock in this offering	\$ _____

If the underwriters exercise their option to purchase additional shares in full, our as adjusted net tangible book value per share after this offering would be \$ _____, representing an immediate increase in as adjusted net tangible book value per share of \$ _____ to existing stockholders and immediate dilution in as adjusted net tangible book value per share of \$ _____ to new investors purchasing common stock in this offering, based on the assumed public offering price of \$ _____ per share, the last reported trading price of our common stock on the Nasdaq Global Market on _____, 2020, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The table and discussion above are based on the number of shares of our common stock outstanding as of December 31, 2019, and exclude:

- 5,176,944 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2019 under our 2010 Plan and our 2019 Plan, with a weighted-average exercise price of \$7.35 per share;
- 66,801 shares of common stock reserved for vesting of restricted stock units outstanding as of December 31, 2019 under our 2019 Plan;
- 36,466 shares of common stock available for future issuance as of December 31, 2019 under our 2019 Plan; and

- 237,181 shares of our common stock available for future issuance as of December 31, 2019 under our 2019 Employee Stock Purchase Plan, or our 2019 ESPP.

To the extent that outstanding stock options are exercised, new stock options are issued or we issue additional shares of common stock in the future, there will be further dilution to new investors. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

PRINCIPAL STOCKHOLDERS

The following table sets forth information, to the extent known by us or ascertainable from public filings, with respect to the beneficial ownership of our common stock (1) as of March 31, 2020 and (2) as adjusted to reflect the sale of common stock offered by us in this offering, by:

- each of our directors;
- each of our named executive officers;
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, who is known by us to be a beneficial owner of greater-than-5.0% of our common stock.

The percentage ownership information shown in the table prior to this offering is based upon 23,188,816 shares of our common stock outstanding as of March 31, 2020. The percentage ownership information shown in the table after this offering is based upon 23,188,816 shares of common stock outstanding as of March 31, 2020, as adjusted to reflect the sale of _____ shares of common stock by us in the offering and assuming no exercise of the underwriters' option to purchase additional shares. As of March 31, 2020, we had approximately 38 holders of record.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. Shares of our common stock subject to options that are currently exercisable or exercisable within 60 days of March 31, 2020 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise

indicated in the table below, addresses of named beneficial owners are in care of Axcella Health Inc., 840 Memorial Drive, Cambridge, Massachusetts 02139.

Name and address of beneficial owner	Shares beneficially owned prior to the offering		Shares beneficially owned after the offering	
	Number	Percentage	Number	Percentage
5% Stockholders:				
Flagship Pioneering Funds(1)	8,748,414	37.7%		
FMR LLC(2)	3,211,922	13.9%		
Nestlé Health Sciences US Holdings, Inc.(3)	2,368,699	10.2%		
Gurnet Point L.P.(4)	1,293,891	5.6%		
HarbourVest Partners L.P.(5)	1,229,034	5.3%		
Named executive officers and directors:				
David R. Epstein(6)	602,455	2.5%		
William Hinshaw(7)	484,713	2.0%		
Manu Chakravarthy, M.D., Ph.D.(8)	163,337	*		
William D. Baird III(9)	33,324	*		
Grégory Behar, M.B.A.(10)	11,000	*		
David A. Berry, M.D., Ph.D.(11)	771,042	3.3%		
Shreeram Aradhye, M.D.(12)	61,074	*		
Stephen Hoge, M.D.(13)	65,288	*		
Gary Pisano, Ph.D.(14)	92,433	*		
Cristina M. Rondinone, Ph.D.(15)	31,185	*		
Catherine A. Sohn, PharmD.(16)	6,499	*		
All executive officers and directors as a group (16 persons)(17)	2,598,734	10.4%		

* Represents beneficial ownership of less than one percent.

- (1) Based solely on a Schedule 13D filed with the SEC on May 23, 2019, consists of (i) 2,035,830 shares of common stock held by Flagship VentureLabs IV, LLC ("VentureLabs IV") (ii) 1,761,029 shares of common stock held by Flagship Ventures Fund 2007, L.P. ("Flagship Fund 2007"), (iii) 3,288,780 shares of common stock held by Flagship Ventures Fund IV, L.P. ("Flagship Fund IV"), (iv) 676,752 shares of common stock held by Flagship Ventures Fund IV Rx, L.P. ("Flagship Fund IV Rx" and, together with VentureLabs IV and Flagship Fund IV, the "Flagship IV Funds") and (v) 986,023 shares of common stock held by Flagship Ventures Opportunities Fund I, L.P. ("Flagship Opportunities I"). Noubar B. Afeyan, Ph.D. and Edwin M. Kania are the managers of the general partner of Flagship Fund IV and Flagship Fund 2007, and each of these individuals may be deemed to beneficially own the shares directly held by the Flagship Fund IV Funds and Flagship Fund 2007. While Mr. Kania is retired from Flagship Pioneering, he continues to serve as a manager of Flagship Fund IV GP and Flagship Fund 2007 GP. Dr. Afeyan, as the sole manager of the general partner of Flagship Opportunities I, may be deemed to beneficially own the shares directly held by Flagship Opportunities I. The address of each of the entities and individuals listed above is 55 Cambridge Parkway, Suite 800E, Cambridge, MA 02142.
- (2) Based solely on a Schedule 13G/A filed with the SEC on February 7, 2020, FMR LLC has sole voting power with respect to 950,165 shares and sole dispositive power over 3,211,922 shares and Abigail P. Johnson has sole dispositive power over 3,211,922 shares. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of

FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act ("Fidelity Funds") advised by Fidelity Management & Research Company ("FMR Co"), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. FMR Co carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. The address of FMR LLC is 245 Summer Street, Boston, Massachusetts 02210.

- (3) Based solely on a Schedule 13G filed with the SEC on February 13, 2020, (i) Nestlé Health Science US Holdings, Inc. ("NHS"), (ii) NIMCO US, Inc. ("NIMCO"), the parent of NHS, (iii) Nestlé US Holdco, Inc. ("Nestlé US Holdco"), an indirect parent of NHS, (iv) Société des Produits Nestlé S.A. ("SPN"), an indirect parent of NHS, and (v) Nestlé S.A. ("Nestlé"), the ultimate parent of each of NHS, NIMCO, Nestlé US Holdco and SPN, each has shared voting power and shared dispositive power with respect to 2,368,699 shares. The principal executive office of NHS, NIMCO and Nestlé US Holdco is 1812 North Moore Street, Arlington, VA 22209 and the principal executive office of SPN and Nestlé is Avenue Nestlé 55, CH-1800, Vevey Switzerland.
- (4) Based solely on a Schedule 13G filed with the SEC on February 7, 2020, Gurnet Point L.P. ("Gurnet Point") and Waypoint International GP LLC ("Waypoint"), the general partner of Gurnet Point, each has shared voting power and shared dispositive power with respect to 1,293,891 shares. The address of Gurnet Point and Waypoint is 55 Cambridge Parkway, Suite 401, Cambridge, Massachusetts 02142.
- (5) Based solely on a Schedule 13G filed with the SEC on February 5, 2020, consists of 1,229,034 shares common stock owned directly by SMRS-TOPE LLC. HarbourVest Partners, LLC ("HarbourVest") is the General Partner of HarbourVest Partners L.P., which is the Manager of HVST-TOPE LLC, which is the Managing Member of SMRS-TOPE LLC. Each of HarbourVest, HarbourVest Partners L.P. and HVST-TOPE LLC may be deemed to have a beneficial interest in the shares held by SMRS-TOPE LLC. Voting and investment power over the securities owned directly by SMRS-TOPE LLC is exercised by the Investment Committee of HarbourVest. Each of HarbourVest, HarbourVest Partners L.P. and HVST-TOPE LLC and the members of the HarbourVest Investment Committee disclaim beneficial ownership of the shares held directly by SMRS-TOPE LLC. The principal business office of each HarbourVest, HarbourVest Partners L.P., HVST-TOPE LLC and SMRS-TOPE LLC is One Financial Center, Boston, MA 02111.
- (6) Consists of 68,103 shares of common stock and 534,352 shares of common stock underlying options exercisable within 60 days of March 31, 2020.
- (7) Consists of 484,713 shares of common stock underlying options exercisable within 60 days of March 31, 2020.
- (8) Consists of 163,337 shares of common stock underlying options exercisable within 60 days of March 31, 2020.
- (9) Consists of 33,324 shares of common stock underlying options exercisable within 60 days of March 31, 2020.
- (10) Consists of 11,000 shares of common stock underlying options exercisable within 60 days of March 31, 2020.

- (11) Consists of 760,042 shares of common stock and 11,000 shares of common stock underlying options exercisable within 60 days of March 31, 2020. Mr. Berry, who is currently a Class I director, has not been nominated for re-election to the board of directors at the Annual Meeting, and his term will end as of the close of the Annual Meeting.
- (12) Consists of 61,074 shares of common stock underlying options exercisable within 60 days of March 31, 2020.
- (13) Consists of 65,288 shares of common stock underlying options exercisable within 60 days of March 31, 2020.
- (14) Consists of 92,433 shares of common stock underlying options exercisable within 60 days of March 31, 2020.
- (15) Consists of 31,185 shares of common stock underlying options exercisable within 60 days of March 31, 2020.
- (16) Consists of 1,000 shares of common stock and 5,499 shares of common stock underlying options exercisable within 60 days of March 31, 2020.
- (17) Also includes an aggregate of 3,665 shares of common stock and 272,719 shares of common stock underlying options exercisable within 60 days of March 31, 2020 held by Laurent Chardonnet, Stephen Mitchener, PharmD., Tony Tramontin, Ph.D., Paul Fehlner, J.D., Ph.D., and Heidy King-Jones, J.D., LL.M.

DESCRIPTION OF CAPITAL STOCK

The summary of the general terms and provisions of our registered securities set forth below does not purport to be complete. It is subject to and qualified in its entirety by reference to our Restated Certificate of Incorporation, or our Certificate of Incorporation, and our Amended and Restated Bylaws, or our Bylaws, each of which are incorporated by reference as an exhibit to the registration statement of which this prospectus forms a part, and by applicable law. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of the Delaware General Corporation Law for additional information.

Authorized Capital Stock

Our authorized capital stock consists of 150,000,000 shares of common stock, \$0.001 par value per share, and 10,000,000 shares of preferred stock, \$0.001 par value per share, all of which are undesignated preferred stock.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights, or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. All outstanding shares are fully paid and nonassessable.

Listing

Our common stock is listed and traded on the Nasdaq Global Market under the symbol "AXLA."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to designate and issue up to 10,000,000 shares of preferred stock in one or more series. Our board of directors may also designate the rights, preferences and privileges of the holders of each such series of preferred stock, any or all of which may be greater than or senior to those granted to the holders of common stock. While, the issuance of preferred stock provides flexibility in connection with possible future financings and acquisitions and other corporate purposes, the rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future. Though the actual effect of any such issuance on the rights of the holders of common stock will not be known until such time as our board of directors determines the specific rights of the holders of preferred stock, the issuance of preferred stock could have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying, deferring or preventing a change in control of our company, which might harm the market price of our common stock.

No shares of preferred stock are outstanding as of the date hereof.

Anti-Takeover Effects of Delaware Law and Provisions of our Charter Documents

Certain provisions of the Delaware General Corporation Law and of our Charter Documents could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of us to first negotiate with our board of directors. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we believe that the advantages gained by protecting our ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our common stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge, exchange, mortgage or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Charter Documents

Our Charter Documents include a number of provisions that may have the effect of encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies. In accordance with our Certificate of Incorporation, our board is divided into three classes serving three-year terms, with one class being elected each year. Our Certificate of Incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds ($\frac{2}{3}$) or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office, even if less than a quorum.

No Written Consent of Stockholders. Our Certificate of Incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting.

Meetings of Stockholders. Our by-laws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our by-laws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements. Our by-laws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days or more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. The notice must contain certain information specified in the by-laws. These provisions may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed. These provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

Amendment to By-laws and Certificate of Incorporation. As required by the Delaware General Corporation Law, any amendment of our Certificate of Incorporation must first be approved by a majority of our board of directors and, if required by law or our Certificate of Incorporation, thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, directors, limitation of liability, exclusive jurisdiction of Delaware Courts and the amendment of our by-laws and Certificate of Incorporation must be approved by not less than two-thirds ($\frac{2}{3}$) of the outstanding shares entitled to vote on the amendment, and not less than two-thirds ($\frac{2}{3}$) of the outstanding shares of each class entitled to vote thereon as a class. Our by-laws may be amended by the affirmative vote of a majority of the directors then in office, subject to

any limitations set forth in the by-laws; and may also be amended by the affirmative vote of at least two-thirds ($\frac{2}{3}$) of the outstanding shares entitled to vote on the amendment, or, if the board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Blank Check Preferred Stock. Our Certificate of Incorporation provides for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of us or our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our Certificate of Incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Choice of Forum. Our Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our Certificate of Incorporation or Bylaws; (4) any action to interpret, apply, enforce or determine the validity of our Certificate of Incorporation or Bylaws or (5) any action asserting a claim governed by the internal affairs doctrine. The choice of forum provision does not apply to any actions arising under the Securities Act or the Exchange Act.

CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a foreign corporation or any other foreign organization taxable as a corporation for U.S. federal income tax purposes; or
- a foreign estate or trust, the income of which is not subject to U.S. federal income tax on a net income basis.

This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons that hold their common stock through partnerships or other pass-through entities. A partner in a partnership or an investor in any other pass-through entity that will hold our common stock should consult his, her or its tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the Internal Revenue Code of 1986 as amended, or the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any such change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the Internal Revenue Service, or the IRS, will not challenge one or more of the tax consequences described herein. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment).

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances including the alternative minimum tax, the Medicare tax on net investment income, and any election to apply Section 1400Z-2 of the Code to gains recognized with respect to shares of our common stock. This discussion also does not address any U.S. state, local or non-U.S. taxes or any other aspect of any U.S. federal tax other than the income tax. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt or governmental organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;

- "qualified foreign pension funds," or entities wholly owned by a "qualified foreign pension fund";
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and partners and investors therein);
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- persons who have elected to mark securities to market;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons for whom our stock constitutes "qualified small business stock" within the meaning of Section 1202 of the Code
- certain U.S. expatriates; and
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the common stock being taken into account in an applicable financial statement under Section 451(b) of the Code.

This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

Distributions on our common stock

Distributions, if any, on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "Gain on sale or other taxable disposition of our common stock." Any such distributions will also be subject to the discussions below under the sections titled "Backup withholding and information reporting" and "Withholding and information reporting requirements—FATCA."

Subject to the discussion in the following two paragraphs in this section, dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. If we or another withholding agent apply over-withholding or if a non-U.S. holder does not timely provide us with the required certification, the non-U.S. holder may be entitled to a refund or credit of any excess tax withheld by timely filing an appropriate claim with the IRS.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income

received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) to the applicable withholding agent and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

Gain on sale or other taxable disposition of our common stock

Subject to the discussions below under "Backup withholding and information reporting" and "Withholding and information reporting requirements—FATCA," a non-U.S. holder generally will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale or other taxable disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Distributions on our common stock" also may apply;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- we are, or have been, at any time during the five-year period preceding such sale or other taxable disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Backup withholding and information reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to

establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in "Distributions on our common stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them. Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS in a timely manner.

Withholding and information reporting requirements—FATCA

Provisions of the Code commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally impose a U.S. federal withholding tax at a rate of 30% on payments of dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. Under applicable U.S. Treasury regulations, withholding under FATCA currently applies to payments of dividends on our common stock. Currently proposed U.S. Treasury Regulations provide that FATCA withholding does not apply to gross proceeds from the disposition of property of a type that can produce U.S. source dividends or interest, such as our common stock; however, prior versions of the rules would have made such gross proceeds subject to FATCA withholding. Taxpayers (including withholding agents) can currently rely on the proposed Treasury Regulations. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of this withholding tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

UNDERWRITING

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC and SVB Leerink LLC are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

<u>Name</u>	<u>Number of Shares</u>
J.P. Morgan Securities LLC	
SVB Leerink LLC	
Total	

The underwriters are committed to purchase all of the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to initially offer the shares of common stock directly to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ per share. Any such dealers may resell shares to certain other brokers or dealers at a discount of up to \$ per share from the initial public offering price. After the initial offering of the shares to the public, if all of the shares of common stock are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of any shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is \$ per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	<u>Without option to purchase additional shares exercise</u>	<u>With full option to purchase additional shares exercise</u>
Per Share	\$	\$
Total	\$	\$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately \$. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to \$.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that, subject to certain limited exceptions, we will not (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with, the Securities and Exchange Commission a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exercisable or exchangeable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, loan, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC and SVB Leerink LLC for a period of 90 days after the date of this prospectus, other than the shares of our common stock to be sold in this offering.

Our directors and executive officers (such persons, the "lock-up parties") have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each lock-up party, with limited exceptions, for a period of 90 days after the date of this prospectus (such period, the "restricted period"), may not, without the prior written consent of the representatives: (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock beneficially owned in accordance with the rules and regulations of the SEC (including without limitation, shares of common stock and other securities convertible into or exercisable or exchangeable for common stock, in each case, that are issued or issuable upon exercise of a stock option or warrant so owned), or publicly disclose the intention to make any offer, sale, pledge or disposition, (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common stock or such other securities described in clause (1) above, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or such other securities, in cash or otherwise.

The representatives, in their sole discretion, may release the securities subject to any of the lock-up agreements with the underwriters described above, in whole or in part at any time.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

Our common stock is listed on the Nasdaq Global Market under the symbol "AXLA".

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of common stock,

which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act of 1933, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the Nasdaq Global Market, in the over-the-counter market or otherwise.

In addition, in connection with this offering certain of the underwriters (and selling group members) may engage in passive market making transactions in our common stock on the Nasdaq Global Market prior to the pricing and completion of this offering. Passive market making consists of displaying bids on the Nasdaq Global Market no higher than the bid prices of independent market makers and making purchases at prices no higher than these independent bids and effected in response to order flow. Net purchases by a passive market maker on each day are generally limited to a specified percentage of the passive market maker's average daily trading volume in the common stock during a specified period and must be discontinued when such limit is reached. Passive market making may cause the price of our common stock to be higher than the price that otherwise would exist in the open market in the absence of these transactions. If passive market making is commenced, it may be discontinued at any time.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory,

investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Notice to Prospective Investors in the European Economic Area and United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom (each a "Relevant State"), no shares have been offered or will be offered pursuant to this offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and the company that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons") or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (the "SFO") of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong) (the "CO") or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made thereunder.

Notice to Prospective Investors in Singapore

Each underwriter has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each underwriter has represented and agreed that it has not offered or sold any shares or caused the shares to be made the subject of an invitation for subscription or purchase and will not offer or sell any shares or cause the shares to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, whether directly or indirectly, to any person in Singapore other than:

- (a) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the "SFA")) pursuant to Section 274 of the SFA;

- (b) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA; or
- (c) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:
- (i) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- (ii) where no consideration is or will be given for the transfer;
- (iii) where the transfer is by operation of law;
- (iv) as specified in Section 276(7) of the SFA; or
- (v) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the shares nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any "resident" of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. Certain legal matters related to this offering will be passed upon for the underwriters by Latham & Watkins LLP.

EXPERTS

The financial statements incorporated in this prospectus by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2019 have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference. Such financial statements have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 (File Number 333-) under the Securities Act with respect to the common stock we are offering by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our common stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

We are subject to the informational requirements of the Exchange Act and file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at www.sec.gov. We also maintain a website at <https://www.axcellahealth.com/>. You may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendment to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. We do not incorporate the information on our website into this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus or any supplement to this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus).

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus. We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we have filed with the SEC (File No. 001-38901):

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 23, 2020;
- the information specifically incorporated by reference into our Annual Report on Form 10-K for the year ended December 31, 2019 from our definitive proxy statement on Schedule 14A (other than information furnished rather than filed), which was filed with the SEC on April 3, 2020;
- our Current Reports on Form 8-K filed with the SEC on _____, in each case to the extent the information in such reports is filed and not furnished; and
- the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on May 7, 2019, including any amendments or reports filed for the purposes of updating this description.

Notwithstanding the statements in the preceding paragraphs, no document, report or exhibit (or portion of any of the foregoing) or any other information that we have "furnished" to the SEC pursuant to the Exchange Act shall be incorporated by reference into this prospectus.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference in this prospectus, including exhibits to these documents. You should direct any requests for documents to Axcella Health Inc., Attn: Corporate Secretary, 840 Memorial Drive, Cambridge, MA 02139.

You also may access these filings on our website at <https://www.axcellahealth.com/>. We do not incorporate the information on our website into this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus or any supplement to this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus).

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.

Shares



Axcella Health Inc.

Common Stock

PRELIMINARY PROSPECTUS

J.P. MORGAN

SVB LEERINK

PART II**INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the fees and expenses, other than underwriting discounts and commissions, payable in connection with the registration of the common stock hereunder. All amounts are estimates except the SEC registration fee and the FINRA filing fee.

	Amount to be Paid
SEC registration fee	\$ *
FINRA filing fee	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous	*
Total	\$ *

* To be provided by amendment

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law, or the DGCL, authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our restated certificate of incorporation and amended and restated bylaws that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for any breach of the director's duty of loyalty to us or our stockholders; any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law; any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our amended and restated bylaws provide that we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and certain of our executive officers. These agreements will provide that we will indemnify each of our directors, certain of our executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us or in furtherance of our rights. Additionally, certain of our directors or officers may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates or other third parties, which indemnification relates to and might apply to the same proceedings arising out of such director's or officer's services as a director referenced herein. Nonetheless, we will agree in the indemnification agreements that our obligations to those same directors or officers are primary and any obligation of such affiliates or other third parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We will maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended, or the Securities Act.

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of us and our directors and officers by the underwriters against certain liabilities under the Securities Act and the Securities Exchange Act of 1934.

Item 15. Recent Sales of Unregistered Securities.

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act:

(a) Issuances of Capital Stock

In August 2017, we issued and sold to investors in a private placement an aggregate of 2,572,420 shares of our Series C Preferred Stock at a purchase price of \$10.08 per share, for aggregate consideration of approximately \$25,930,000.

In November 2018, we issued we issued and sold to investors in a private placement an aggregate of 5,282,002 shares of our Series E Preferred Stock at a purchase price of \$11.17 per share, for aggregate consideration of approximately \$59,000,000.

No underwriters were involved in the foregoing sales of securities. The sales of securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering. All of the purchasers in these transactions represented to us in connection with their purchase that they were acquiring the securities for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. Such purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities were deemed restricted securities for the purposes of the Securities Act.

On May 13, 2019, upon the closing of our initial public offering, all 26,831,246 shares of our then-outstanding redeemable convertible preferred stock automatically converted into 14,641,997 shares of common stock. The issuance of such common stock was exempt from the registration requirements of the Securities Act, pursuant to Section 3(a)(9) of the Securities Act, involving an exchange of securities exchanged by the issuer with its existing security holders exclusively where no commission or

other remuneration is paid or given directly or indirectly for soliciting such exchange. No underwriters were involved in this issuance of shares.

(b) Grants and Exercises of Stock Options

Between April 1, 2017 and the filing of our registration statement on Form S-8 on May 17, 2019, we granted stock options to purchase an aggregate of 3,779,269 shares of our common stock, with exercise prices ranging from \$6.21 to \$13.83 per share, to employees, directors and consultants pursuant to the 2010 Plan, and an aggregate of 8,514 shares of common stock were issued upon the exercise of stock options pursuant to the 2010 Plan.

The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The shares of common stock issued upon the exercise of options are deemed to be restricted securities for purposes of the Securities Act.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

- 1.1* Form of Underwriting Agreement
- 3.1 Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.3 to the Registrant's Current Report on Form 8-K (File No. 001-38901) filed with the Securities and Exchange Commission on May 13, 2019).
- 3.2 Amended and Restated Bylaws of Registrant (Incorporated by reference to Exhibit 3.4 to the Registrant's Current Report on Form 8-K (File No. 001-38901) filed with the Securities and Exchange Commission on May 13, 2019).
- 4.1 Specimen Stock Certificate evidencing shares of common stock (Incorporated by reference to Exhibit 4.1 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1/A (File No. 333-230822) filed with the Securities and Exchange Commission on April 30, 2019).
- 4.2 Fifth Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated November 30, 2018 (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-230822) filed with the Securities and Exchange Commission on April 12, 2019).
- 5.1* Opinion of Goodwin Procter LLP
- 10.1# 2010 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-230822) filed with the Securities and Exchange Commission on April 30, 2019).
- 10.2# 2019 Stock Option and Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Amendment No. 2 to the Registration Statement on Form S-1 (File No. 333-230822) filed with the Securities and Exchange Commission on May 6, 2019).
- 10.3# 2019 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-230822) filed with the Securities and Exchange Commission on April 30, 2019).

- 10.4# Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-230822) filed with the Securities and Exchange Commission on April 30, 2019).
- 10.5# Amended and Restated Employment Agreement between the Registrant and William Hinshaw, dated December 20, 2018 (incorporated by reference to Exhibit 10.5 to the Registrant's Amendment No. 2 to the Registration Statement on Form S-1 (File No. 333-230822) filed with the Securities and Exchange Commission on May 6, 2019).
- 10.6# Employment Agreement between the Registrant and Shreeram Aradhya, dated January 1, 2019 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 12, 2019).
- 10.7#* Amended and Restated Employment Agreement between the Registrant and Manu Chakravarthy, dated December 29, 2018.
- 10.8# Amended and Restated Employment Agreement between the Registrant and Stephen Mitchener, dated December 29, 2018 (incorporated by reference to Exhibit 10.7 to the Registrant's Amendment No. 2 to the Registration Statement on Form S-1 (File No. 333-230822) filed with the Securities and Exchange Commission on May 6, 2019).
- 10.9# Employment Agreement between the Registrant and Laurent Chardonnet, dated November 11, 2019. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38901) filed with the Securities and Exchange Commission on November 25, 2019).
- 10.10# Chairman and Consulting Agreement between the Registrant and the Chairman of the Board of Directors, dated August 22, 2019 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 12, 2019).
- 10.11# Form of Indemnification Agreement between the Registrant and each of its directors (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-230822) filed with the Securities and Exchange Commission on April 12, 2019).
- 10.12# Form of Indemnification Agreement between the Registrant and each of its executive officers (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-230822) filed with the Securities and Exchange Commission on April 12, 2019).
- 10.13 Riverside Technology Center Commercial Lease Agreement between Rivertech Associates II, LLC and the Registrant, dated as of December 28, 2010 (incorporated by reference to Exhibit 10.10 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-230822) filed with the Securities and Exchange Commission on April 30, 2019).
- 10.14 Fifth Lease Extension and Modification Agreement to the Lease Agreement between Rivertech Associates II, LLC and the Registrant, dated as of April 28, 2017 (incorporated by reference to Exhibit 10.11 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-230822) filed with the Securities and Exchange Commission on April 30, 2019).

- 10.15 Loan and Security Agreement among Solar Capital Ltd. and the Lenders thereto and the Registrant, dated as of January 9, 2018 (incorporated by reference to Exhibit 10.12 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-230822) filed with the Securities and Exchange Commission on April 30, 2019).
 - 10.16 First Amendment to Loan and Security Agreement, dated October 5, 2018 (incorporated by reference to Exhibit 10.13 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-230822) filed with the Securities and Exchange Commission on April 30, 2019).
 - 10.17 Second Amendment to Loan and Security Agreement, dated November 30, 2018 (incorporated by reference to Exhibit 10.14 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-230822) filed with the Securities and Exchange Commission on April 30, 2019).
 - 21.1 Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K (File No. 001-38501) filed with the Securities and Exchange Commission on March 23, 2020).
 - 23.1* Consent of Deloitte and Touche LLP, Independent Registered Public Accounting Firm
 - 23.2* Consent of Goodwin Procter LLP (included in Exhibit 5.1)
 - 24.1* Power of Attorney (included on signature page to this Registration Statement on Form S-1)
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* To be filed by amendment.

Indicates a management contract or any compensatory plan, contract or arrangement.

(b) Financial Statements Schedules:

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Act, may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The Registrant hereby undertakes that:

(a) The Registrant will provide to the underwriter at the closing as specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(b) For purposes of determining any liability under the Securities Act of 1933, as amended, the information omitted from a form of prospectus filed as part of this registration statement in

reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933, as amended, shall be deemed to be part of this registration statement as of the time it was declared effective.

(c) For the purpose of determining any liability under the Securities Act of 1933, as amended, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, Massachusetts, on the day of , 2020.

AXCELLA HEALTH INC.

By:

Name: William Hinshaw
Title: Chief Executive Officer, President and Director

POWER OF ATTORNEY AND SIGNATURES

Each individual whose signature appears below hereby constitutes and appoints each of William Hinshaw and Laurent Chardonnet as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement (or any Registration Statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement and Power of Attorney has been signed by the following persons in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
_____ William Hinshaw	Chief Executive Officer, President and Director (Principal Executive Officer)	
_____ Laurent Chardonnet	Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	
_____ David R. Epstein	Chairman, Director	
_____ Grégory Behar	Director	

<u>Name</u>	<u>Title</u>	<u>Date</u>
David A. Berry, M.D., Ph.D.	Director	
William D. Baird III	Director	
Stephen Hoge, M.D.	Director	
Gary Pisano, Ph.D.	Director	
Cristina M. Rondinone, Ph.D.	Director	
Catherine A. Sohn, Pharm.D.	Director	

