CYTOKINETICS INC
Form 10-K
March 06, 2017
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2016

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
From the transition period from_____ to _____

Commission file number: 000-50633

CYTOKINETICS, INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware	**94-3291317**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
280 East Grand Avenue	
South San Francisco, CA	**94080**
(Address of principal executive offices)	*(Zip Code)*

(650) 624-3000

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $0.001 par value	The NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of the Registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of the voting and non-voting common equity held by non-affiliates was $375.5 million, computed by reference to the last sales price of $9.49 as reported by the NASDAQ Market as of June 30, 2016. This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any other purpose. The number of shares of common stock held by non-affiliates excluded 130,998 shares of common stock held by directors, officers and affiliates of directors. The number of shares owned by affiliates of directors was determined based upon information supplied by such persons and upon Schedules 13D and 13G, if any, filed with the SEC. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant, that such person is controlled by or under common control with the Registrant, or that such persons are affiliates for any other purpose.

The number of shares outstanding of the Registrant s common stock on February 23, 2017 was 41,729,549 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant s Proxy Statement for its 2017 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission, no later than 120 days after the end of the fiscal year, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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CYTOKINETICS, INCORPORATED

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PART I

This report contains forward-looking statements indicating expectations about future performance and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), and the Private Securities Litigation Reform Act of 1995, that involve risks and uncertainties. We intend that such statements be protected by the safe harbor created thereby. Forward-looking statements involve risks and uncertainties and our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Examples of such forward-looking statements include, but are not limited to, statements about or relating to:

- guidance concerning revenues, research and development expenses and general and administrative expenses for 2017;
- the sufficiency of existing resources to fund our operations for at least the next 12 months;
- our capital requirements and needs for additional financing;
- the initiation, design, conduct, enrollment, progress, timing and scope of clinical trials and development activities for our drug candidates conducted by ourselves or our partners, Amgen Inc. (Amgen) and Astellas Pharma Inc. (Astellas), including the anticipated timing for initiation of clinical trials, anticipated rates of enrollment for clinical trials and anticipated timing of results becoming available or being announced from clinical trials;
- the results from the clinical trials, the non-clinical studies and chemistry, manufacturing, and controls (CMC) activities of our drug candidates and other compounds, and the significance and utility of such results;
- anticipated interactions with regulatory authorities;
- the further development of tirasemtiv for the potential treatment of amyotrophic lateral sclerosis (ALS);
- the expected acceptability by regulatory authorities of the effects of tirasemtiv on slow vital capacity or other measures of clinical benefit related to respiratory function in patients with ALS as Phase 3 clinical trial endpoints to support the registration of tirasemtiv as a treatment for ALS;
- our and our partners plans or ability to conduct the continued research and development of our drug candidates and other compounds;

the advancement of omecamtiv mecarbil in Phase 3 clinical development;

our expected roles in research, development or commercialization under our strategic alliances with Amgen and Astellas;

the properties and potential benefits of, and the potential market opportunities for, our drug candidates and other compounds, including the potential indications for which they may be developed;

the sufficiency of the clinical trials conducted with our drug candidates to demonstrate that they are safe and efficacious;

our receipt of milestone payments, royalties, reimbursements and other funds from current or future partners under strategic alliances, such as with Amgen or Astellas;

our ability to continue to identify additional potential drug candidates that may be suitable for clinical development;

our plans or ability to commercialize drugs with or without a partner, including our intention to develop sales and marketing capabilities;

the focus, scope and size of our research and development activities and programs;

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the utility of our focus on the biology of muscle function, and our ability to leverage our experience in muscle contractility to other muscle functions;

our ability to protect our intellectual property and to avoid infringing the intellectual property rights of others;

future payments and other obligations under loan and lease agreements;

potential competitors and competitive products;

retaining key personnel and recruiting additional key personnel; and

the potential impact of recent accounting pronouncements on our financial position or results of operations.

Such forward-looking statements involve risks and uncertainties, including, but not limited to:

further clinical development of tirasemtiv for the potential treatment of ALS will require significant additional funding and we may be unable to obtain such additional funding on acceptable terms, if at all;

the U.S. Food and Drug Administration (FDA) and/or other regulatory authorities may not accept effects on respiratory function, including slow vital capacity, as appropriate clinical trial endpoints to support the registration of tirasemtiv for the treatment of ALS;

Amgen s decisions with respect to the timing, design and conduct of research and development activities for omecamtiv mecarbil and related compounds, including decisions to postpone or discontinue research or development activities relating to omecamtiv mecarbil and related compounds;

Astellas decisions with respect to the timing, design and conduct of research and development activities for CK-2127107 and other skeletal muscle activators, including decisions to postpone or discontinue research or development activities relating to CK-2127107 and other skeletal muscle activators, as well as Astellas decisions with respect to its option to enter into a global collaboration for the development and commercialization of tirasemtiv;

our ability to enter into strategic partnership agreements for any of our programs on acceptable terms and conditions or in accordance with our planned timelines;

our ability to obtain additional financing on acceptable terms, if at all;

our receipt of funds and access to other resources under our current or future strategic alliances;

difficulties or delays in the development, testing, manufacturing or commercialization of our drug candidates;

difficulties or delays, or slower than anticipated patient enrollment, in our or partners clinical trials;

difficulties or delays in the manufacture and supply of clinical trial materials;

failure by our contract research organizations, contract manufacturing organizations and other vendors to properly fulfill their obligations or otherwise perform as expected;

results from non-clinical studies that may adversely impact the timing or the further development of our drug candidates and other compounds;

the possibility that the FDA or foreign regulatory agencies may delay or limit our or our partners ability to conduct clinical trials or may delay or withhold approvals for the manufacture and sale of our products;

changing standards of care and the introduction of products by competitors or alternative therapies for the treatment of indications we target that may limit the commercial potential of our drug candidates;

difficulties or delays in achieving market access and reimbursement for our drug candidates and the potential impacts of health care reform;

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changes in laws and regulations applicable to drug development, commercialization or reimbursement;

the uncertainty of protection for our intellectual property, whether in the form of patents, trade secrets or otherwise;

potential infringement or misuse by us of the intellectual property rights of third parties;

activities and decisions of, and market conditions affecting, current and future strategic partners;

accrual information provided by our contract research organizations (CROs), contract manufacturing organizations (CMOs), and other vendors;

potential ownership changes under Internal Revenue Code Section 382; and

the timeliness and accuracy of information filed with the U.S. Securities and Exchange Commission (the SEC) by third parties.

In addition, such statements are subject to the risks and uncertainties discussed in the Risk Factors section and elsewhere in this document. Such statements speak only as of the date on which they are made, and, except as required by law, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Item 1. *Business*

When used in this report, unless otherwise indicated, Cytokinetics, the Company, we, our and us re Cytokinetics, Incorporated. CYTOKINETICS, and our logo used alone and with the mark CYTOKINETICS, are registered service marks and trademarks of Cytokinetics. Other service marks, trademarks and trade names referred to in this report are the property of their respective owners.

Overview

We were incorporated in Delaware in August 1997 as Cytokinetics, Incorporated. We are a late-stage biopharmaceutical company focused on the discovery and developments of first-in-class muscle activators as potential treatment for debilitating diseases in which muscle performance is compromised and/or declining. Our research and development activities relating to the biology of muscle function have evolved from our knowledge and expertise regarding the cytoskeleton, a complex biological infrastructure that plays a fundamental role within every human cell. Our most advanced research and development programs relate to the biology of muscle function and are directed to small molecule modulators of the contractility of skeletal or cardiac muscle. We are also conducting earlier-stage research directed to other compounds with the potential to modulate muscle contractility and other muscle functions.

Our lead drug candidate from our skeletal muscle contractility program, tirasemtiv (formerly known as CK-2017357), is a fast skeletal troponin activator. We retain exclusive rights to tirasemtiv, subject to Astellas exercise of its option for a license to tirasemtiv (Option on Tirasemtiv see *Astellas Option on Tirasemtiv* below). We conducted a Phase 2 clinical development program for tirasemtiv, including a Phase 2b clinical trial in patients with ALS, known as BENEFIT-ALS (Blinded Evaluation of Neuromuscular Effects and Functional Improvement with Tirasemtiv in ALS). Based on the results of BENEFIT-ALS, we started a Phase 3 clinical development program for tirasemtiv in patients with ALS in July 2015 known as VITALITY-ALS (Ventilatory Investigation of Tirasemtiv and Assessment of Longitudinal Indices after Treatment for a Year in ALS). Tirasemtiv has been granted orphan drug designation and fast track status by the FDA and orphan medicinal product designation by the European Medicines Agency, in each case for the potential treatment of ALS.

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We are also developing CK-2127107, a structurally distinct fast skeletal troponin activator, under a strategic alliance with Astellas. In June 2013, we executed a license and collaboration agreement with Astellas (the Original Astellas Agreement), that was amended and restated in December 2014 (the 2014 Astellas Agreement) and further amended in 2016 (the 2016 Astellas Amendment) collectively with the 2014 Astellas Agreement, the Current Astellas Agreement. The 2016 Astellas Amendment, which became effective in September 2016, expanded our collaboration to include the development of CK-2127107 for the potential treatment of ALS, as well as the possible development in ALS of other fast skeletal regulatory activators licensed to Astellas under the 2014 Astellas Agreement. The 2016 Astellas Amendment also extended the existing joint research program focused on the discovery of additional next-generation skeletal muscle activators through 2017, including sponsored research at Cytokinetics. Finally, under the 2016 Astellas Amendment, the Company granted Astellas the Option on Tirasemtiv, an option to enter into a pre-negotiated agreement for a global collaboration for the development and commercialization of tirasemtiv.

Astellas holds an exclusive license to develop and commercialize CK-2127107 worldwide, subject to our development and commercialization participation rights. Under this strategic alliance, Cytokinetics conducted five Phase 1 clinical trials of CK-2127107 and started a Phase 2 clinical trial of CK-2127107 in patients with spinal muscular atrophy (SMA) in December 2015. CK-2127107 is also being evaluated for the potential use in other indications associated with muscle weakness. Astellas, in collaboration with Cytokinetics, started a Phase 2 clinical trial of CK-2127107 in patients with chronic obstructive pulmonary disease (COPD) in June 2016. We are also conducting joint research with Astellas directed to next-generation skeletal muscle activators. Further details regarding our strategic alliance with Astellas can be found below in Item 1 of this report under Research and Development Programs Skeletal Muscle Contractility Program CK-2127107 and Other Skeletal Muscle Activators Astellas Strategic Alliance.

Our lead drug candidate from our cardiac muscle contractility program, omecamtiv mecarbil (formerly known as CK-1827452), is a novel cardiac muscle myosin activator that is being developed under a strategic alliance with Amgen. Amgen holds an exclusive, worldwide license to omecamtiv mecarbil and related compounds, subject to Cytokinetics specified development and commercialization rights. Amgen has also entered an alliance with Servier for exclusive commercialization rights in Europe as well as the Commonwealth of Independent States (CIS), including Russia. Servier contributes funding for development and provides strategic support to the program.

Omecamtiv mecarbil has been the subject of an extensive Phase 1 and Phase 2 clinical trials program. An intravenous formulation of omecamtiv mecarbil was studied in a Phase 2b clinical trial known as ATOMIC-AHF (Acute Treatment with Omecamtiv Mecarbil to Increase Contractility in Acute Heart Failure), which was designed to evaluate the safety and efficacy of omecamtiv mecarbil in patients with left ventricular systolic dysfunction who are hospitalized with acute heart failure. In October 2015, we announced the results of COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure), the last planned Phase 2 trial of omecamtiv mecarbil to be completed prior to the decision regarding the advancement of this drug candidate to Phase 3. COSMIC-HF was designed to assess the pharmacokinetics and tolerability of omecamtiv mecarbil dosed orally in patients with heart failure and left ventricular systolic dysfunction and its effects on echocardiographic measures of cardiac function. In December 2016, we announced the activation of the first trial site for a Phase 3 cardiovascular outcomes clinical trial of omecamtiv mecarbil conducted by Amgen, GALACTIC-HF (Global Approach to Lowering Adverse Cardiac Outcomes Through Improving Contractility in Heart Failure). Cytokinetics and Amgen are also planning a potential exercise performance/cardiac function clinical trial to be conducted by Cytokinetics; Amgen will be responsible for reimbursing us for the out-of-pocket development costs associated with this clinical trial. Further details regarding our strategic alliance with Amgen can be found below in Item 1 of this report under Research and Development Programs Cardiac Muscle Contractility Program Amgen Strategic Alliance.

All of our drug candidates have demonstrated evidence of potentially clinically relevant pharmacodynamic activity in humans. In 2017, we expect to continue to focus on translating the observed pharmacodynamic activity of these

compounds into potentially meaningful clinical benefits for patients.

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Following is a summary of the planned clinical development activities for our drug candidates:

Drug Candidate (Mechanism of Action)	Partnership Status	Potential Indication(s)	Current Stage of Development	Development Status and Planned Development Activities
Skeletal Muscle Contractility Program				
Tirasemtiv (fast skeletal troponin activator)	Cytokinetics (1)	ALS	Phase 3	We completed enrollment in a Phase 3 clinical trial of tirasemtiv in patients with ALS in the third quarter of 2016 and began an open-label extension trial in the fourth quarter of 2016 for patients who have completed the Phase 3 trial.
CK-2127107 (fast skeletal troponin activator)	Partnered with Astellas	SMA	Phase 2/Phase 1b	We continued enrollment of Cohort 1 of a Phase 2 clinical trial in patients with SMA. We anticipate that the trial will complete enrollment and report data in the second half of 2017.
		COPD		Astellas initiated a Phase 2 clinical trial in patients with COPD in the second quarter of 2016.
		ALS		We anticipate that we will begin a Phase 2 clinical trial in patients with ALS mid-2017.
		Frailty		We anticipate that Astellas will begin a Phase 1b clinical trial in elderly patients with limited mobility in the first half of 2017.
Cardiac Muscle Contractility Program				
Omecamtiv mecarbil (cardiac muscle myosin activator)	Partnered with Amgen	heart failure (oral administration)	Phase 3	Amgen started GALACTIC-HF, a Phase 3 cardiovascular outcomes clinical trial in patients with heart failure with reduced ejection fraction

in December 2016.

(1) Cytokinetics developing independently, subject to Astellas option on tirasemtiv

All of our drug candidates have arisen from our cytoskeletal research activities. Our focus on the biology of the cytoskeleton distinguishes us from other biopharmaceutical companies, and potentially positions us to discover and develop novel therapeutics that may be useful for the treatment of severe diseases and medical conditions. Each of our drug candidates has a novel mechanism of action compared to currently marketed drugs, which we believe validates our focus on the cytoskeleton as a productive area for drug discovery. We intend to leverage our experience in muscle contractility in order to expand our current pipeline, and expect to identify additional potential drug candidates that may be suitable for clinical development.

Corporate Strategy

We are a late-stage biopharmaceutical company focused on the discovery and development and commercialization of first-in-class muscle activators as potential treatment for debilitating diseases in which

muscle performance is compromised and/or declining. As a leader in muscle biology and the mechanics of muscle performance, the company is developing small molecule drug candidates specifically engineered to increase muscle function and contractility. Over the next 5 years, our goal is to discover, develop and commercialize novel drug products that modulate muscle function in ways that may benefit people living with serious diseases or medical conditions, with the intent of establishing a fully integrated biopharmaceutical company.

The five key components of our Corporate Strategy, Vision 2020: Empowering Our Future, are:

Conduct late-stage clinical development of novel, first-in-class muscle activators for the potential treatment of ALS, SMA, heart failure and other diseases impacting muscle function. As we enter 2017, our portfolio consists of three products that are in mid-late stage clinical development in three therapeutic areas, namely ALS, SMA and heart failure. We believe that by focusing on these disease areas characterized by well-organized physician-investigator groups, significant unmet clinical needs, and strong patient and disease advocacy, we may enhance our effectiveness in enrolling and conducting clinical trials that may answer important questions about the dosing, tolerability, pharmacokinetics and pharmacodynamics as well as the potential safety and efficacy of our drug candidates. We believe that our considered clinical trial designs and well-executed development programs can improve our ability to realize value from our and our partners clinical development activities. As we advance our drug candidates into later-stage clinical development, we extensively evaluate previous clinical trial designs and results to assess key learnings that may be applied to our late-stage clinical development activities. We believe this may result in more successful later-stage clinical development activities that may increase the likelihood of achieving our objectives to develop effective therapies that may address the needs of people living with these devastating diseases.

Collaborate with patient communities to support the urgent development of new medicines for diseases of impaired muscle function with pressing unmet medical needs. Central to our corporate strategy are the people living with a disease or medical condition characterized by impaired muscle function. We focused our development and commercialization activities on diseases that lack effective therapies and, in some cases, those with no approved medicines. We recognize that by applying our extensive knowledge of muscle biology towards the development of novel therapies for the people living with these diseases, not only patients but their caregivers and families, we aim to improve their lives. As such, we need to collaborate with these individuals and their communities to ensure our therapeutics are addressing their urgent needs and that we understand and appreciate the issues associated with these diseases and conditions. We work collaboratively with entities, such as patient advocacy groups, that are focused on policies, guidelines and practices to accelerate development and commercialization of novel therapies, where possible and appropriate, and on ensuring that the voice of their constituency is heard.

Mature our company s operations to enable development, registration and commercialization of muscle biology drug candidates across North America and Europe. With a focus on disease areas for which there are serious unmet medical needs, we direct our activities to potential commercial opportunities in concentrated and tractable customer segments, such as hospital specialists and disease-specific centers of excellence, which may be addressed by a smaller, targeted sales force. In preparing for the potential commercialization of our drug candidates directed to these markets, we are focusing our activities on a broad range of issues facing patients and payors, including the principal drivers of clinical and economic burdens associated with these diseases. We also seek to focus on opportunities that the multiple constituencies and stakeholders for these markets may

recognize as creating value. Accordingly, targeting unmet medical needs in these areas may provide us competitive opportunities and support development of a franchise in diseases involving muscle weakness, wasting and fatigue. In these markets, we believe that a company with limited resources may be able to compete effectively against larger, more established companies with greater financial and commercial resources. For these opportunities, we intend to develop clinical development and sales and marketing capabilities in North America and Europe with the goal of becoming a fully integrated biopharmaceutical company.

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Advance next-generation skeletal and cardiac muscle activator compounds into clinical development by leveraging existing research collaborations. We take a purpose-driven approach by leveraging our extensive muscle biology expertise to engineer compounds with specific characteristics aimed at treating diseases that impact muscle function. By increasing muscle strength and performance, the potential treatments we are developing may preserve and extend independence and self-reliance in people suffering from debilitating diseases. We have established select strategic alliances to support our drug development programs while preserving significant development and commercialization rights. We believe that such alliances may allow us to obtain financial support and to capitalize on the therapeutic area expertise and resources of our partners that can potentially accelerate the development and commercialization of our drug candidates. Where we deem appropriate, we plan to retain certain rights to participate in the development of drug candidates and commercialization of potential drugs arising from our programs and alliances, so that we can expand and capitalize on our own internal development capabilities and build our commercialization capabilities.

Progress proprietary research programs focused on muscle into development under new collaborations. We believe that our extensive understanding of muscle biology and our proprietary research technologies should enable us to discover and potentially to develop drug candidates with novel mechanisms of action that may offer potential benefits not provided by existing drugs and which may have application across a broad array of diseases and medical conditions. We expect that we may be able to leverage our expertise in muscle contractility to expand programs related to other areas of muscle function and which may extend to the potential treatment of other serious medical diseases and conditions. Progressing related programs in parallel may afford us an opportunity to build a broader business that could benefit from multiple products that serve related clinical and commercial needs associated with impaired muscle function, muscle weakness and fatigue. In addition, this strategy may enable us to diversify certain technical, financial and operating risks by advancing several drug candidates in parallel.

Research and Development Programs

Our long-standing interest in the cytoskeleton has led us to focus our research and development activities on the biology of muscle function and, in particular, small molecule modulation of muscle contractility. We believe that our expertise in the modulation of muscle contractility is an important differentiator for us. Our preclinical and clinical experience in muscle contractility may position us to discover and develop additional novel therapies that have the potential to improve the health of patients with severe and debilitating diseases or medical conditions.

Small molecules that affect muscle contractility may have several applications for a variety of serious diseases and medical conditions. For example, certain diseases and medical conditions associated with muscle weakness may be amenable to treatment by enhancing the contractility of skeletal muscle. Similarly, heart failure is a disease often characterized by impaired cardiac muscle contractility which may be treated by modulating the contractility of cardiac muscle. Because the modulation of the contractility of different types of muscle, such as cardiac and skeletal muscle, may be relevant to multiple diseases or medical conditions, we believe we can leverage our expertise in these areas to more efficiently discover and develop potential drug candidates that modulate the applicable muscle type for multiple indications.

We are currently developing a number of small molecule compounds arising from our muscle contractility programs.

Tirasemtiv is our lead drug candidate from our skeletal muscle contractility program. Potential indications for which this drug candidate may be useful include skeletal muscle weakness associated with neuromuscular diseases, such as ALS. We have conducted a Phase 2 clinical trials program for tirasemtiv, and completed enrollment in a Phase 3 clinical development program of this drug candidate in patients with ALS in August

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2016. We retain exclusive rights to tirasemtiv, subject to Astellas exercise of its option on tirasemtiv (see *Astellas Option on Tirasemtiv* below).

CK-2127107, another drug candidate from this program, is partnered with Astellas world-wide for the potential treatment of SMA and potentially other neuromuscular and non-neuromuscular indications associated with muscle weakness. We conducted a Phase 1 clinical trials program for CK-2127107 under this collaboration. We started a Phase 2 clinical trial of CK-2127107 in patients with SMA in December 2015. Astellas, in collaboration with Cytokinetics, started a Phase 2 clinical trial of CK-2127107 in patients with COPD in June 2016 and the Company anticipates they will initiate a Phase 1b clinical trial of CK-2127107 in elderly patients with limited mobility in the first half of 2017. We anticipate that we will initiate a Phase 2 clinical trial in patients with ALS mid-2017. Cytokinetics and Astellas continue to evaluate other indications which may be suitable for CK-2127107 or other skeletal sarcomere activators under the collaboration.

Omecamtiv mecarbil, our novel cardiac muscle myosin activator, is partnered with Amgen world-wide. Phase 2 clinical trials were conducted with both intravenous and oral formulations of omecamtiv mecarbil. An intravenous formulation of omecamtiv mecarbil was studied in ATOMIC-AHF, a Phase 2b clinical trial in patients with acute heart failure, and an oral formulation of omecamtiv mecarbil was studied in COSMIC-HF, a Phase 2 clinical trial in patients with heart failure. In December 2016, we announced the start of GALACTIC-HF, a Phase 3 clinical trial which is being conducted by Amgen in collaboration with Cytokinetics. Amgen holds an exclusive, worldwide license to omecamtiv mecarbil and related compounds, subject to Cytokinetics specified development and commercialization rights. Amgen has also entered into an alliance with Servier for exclusive commercialization rights in Europe as well as the CIS, including Russia.

We are continuing to conduct discovery, characterization and lead optimization activities for other compounds with the potential to modulate muscle contractility and other muscle functions.

Research and Development Expense. Our research and development expenses were $59.9 million, $46.4 million and $44.4 million for 2016, 2015 and 2014, respectively.

Skeletal Muscle Contractility Program

Overview

Our skeletal muscle contractility program is focused on the activation of the skeletal sarcomere, the basic unit of skeletal muscle contraction. The skeletal sarcomere is a highly ordered cytoskeletal structure composed of skeletal muscle myosin, actin, and a set of regulatory proteins, which include the troponins and tropomyosin. This program leverages our expertise developed in our ongoing discovery and development of cardiac sarcomere activators, including the cardiac muscle myosin activator omecamtiv mecarbil.

We believe that our skeletal sarcomere activators may lead to new therapeutic options for diseases and medical conditions associated with aging, muscle weakness and wasting and neuromuscular dysfunction. The clinical effects of muscle weakness and wasting, fatigue and loss of mobility can range from decreased quality of life to, in some instances, life-threatening complications. By directly improving skeletal muscle function, a small molecule activator of the skeletal sarcomere potentially could enhance functional performance and quality of life in patients suffering from diseases or medical conditions characterized or complicated by muscle weakness or wasting. These may include diseases and medical conditions associated with skeletal muscle weakness or wasting, such as ALS, claudication, myasthenia gravis, sarcopenia (general frailty associated with aging), post-surgical rehabilitation and cachexia in connection with heart failure or cancer.

Tirasemtiv is our lead drug candidate from this program. We retain exclusive rights to tirasemtiv, subject to Astellas exercise of its Option on Tirasemtiv. We conducted a Phase 2 clinical development program for tirasemtiv, and we started a Phase 3 clinical development program for this drug candidate in patients with ALS in

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July 2015. In collaboration with Astellas, we are also developing another drug candidate from this program, CK-2127107, for potential indications associated with muscle weakness. We started a Phase 2 clinical trial for CK-2127107 in patients with SMA in December 2015. Astellas, in collaboration with Cytokinetics, started a Phase 2 clinical trial of CK-2127107 in patients with chronic obstructive pulmonary disease in June 2016. Tirasemtiv and CK-2127107 are structurally distinct and selective small molecules that activate the fast skeletal troponin complex in the sarcomere by increasing its sensitivity to calcium, leading to an increase in skeletal muscle contractility. Each of tirasemtiv and CK-2127107 has demonstrated pharmacological activity in preclinical models and evidence of potentially clinically relevant pharmacodynamic effects in humans. We are evaluating other potential indications for which tirasemtiv and CK-2127107 may be useful.

Tirasemtiv

Tirasemtiv, a fast skeletal troponin activator, is the lead drug candidate from our skeletal muscle contractility program. We conducted three evidence of effect Phase 2a clinical trials, and a Phase 2b clinical trial of tirasemtiv in patients with ALS. The evidence of effect clinical trials were randomized, double-blind, placebo-controlled, three-period cross-over studies of single doses of tirasemtiv administered to patients with impaired muscle function. These studies were intended to translate the mechanism of action of tirasemtiv into potentially clinically relevant pharmacodynamic effects. The results from the Phase 2b clinical trial, BENEFIT-ALS, of tirasemtiv in patients with ALS showed that effects observed on slow vital capacity (SVC), a measure of the strength of the skeletal muscles responsible for breathing, in patients treated with tirasemtiv were robust and potentially clinically meaningful and supported further evaluation of tirasemtiv in a Phase 3 clinical trial.

Tirasemtiv Clinical Development

VITALITY-ALS: In July 2015, we started VITALITY-ALS, a Phase 3 clinical trial designed to assess the effects of tirasemtiv versus placebo on slow vital capacity and other measures of respiratory function in patients with ALS. VITALITY-ALS is designed to confirm and extend the results observed in BENEFIT-ALS.

VITALITY-ALS is a multi-national, randomized, double-blind, placebo-controlled trial that was originally designed to enroll 445 patients with possible, probable or definite ALS diagnosed within 24 months, and with a baseline vital capacity > 70 % of predicted, based on age, sex, and height. Patients may be enrolled whether, or not they are on riluzole therapy. The primary endpoint of the trial will assess change from baseline in SVC, to be assessed after 24 weeks of double-blind, placebo-controlled treatment. Secondary endpoints include time to decline from baseline in percent predicted SVC by ³ 20 percentage points or the onset of respiratory insufficiency or death; time to decline from baseline in percent predicted SVC to £ 50 percent predicted or the onset of respiratory insufficiency or death; time to first occurrence of any use of assisted ventilation or death; time to decline in any of the three respiratory domains of the ALSFRS-R or death; and change in the Mega-Score of muscle strength.

Patients enrolled in VITALITY-ALS received two-weeks of open-label treatment with tirasemtiv administered at 250 mg/day and were randomized to double-blind treatment with placebo or one of three target tirasemtiv dose levels (250 mg/day, 375 mg/day, 500 mg/day) in a 3:2:2:2 ratio for a total of 48 weeks of randomized, double-blind, placebo-controlled treatment. Then in a four-week double-blind, tirasemtiv withdrawal phase, patients on tirasemtiv are randomized either to continue the double-blind tirasemtiv dose they were receiving or to be withdrawn to placebo in a 1:1 ratio. Patients who had been receiving placebo during the 48 weeks of double-blind, placebo-controlled treatment will continue to receive placebo. VITALITY-ALS is being conducted in 81 centers in 11 countries in North America and Europe and includes most of the sites which participated in BENEFIT-ALS.

The design of VITALITY-ALS addresses certain observations from BENEFIT-ALS. VITALITY-ALS provides for a longer open label phase (one week in BENEFIT-ALS versus two weeks in VITALITY-ALS) prior

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to patient randomization. The longer open label phase in VITALITY-ALS provides more time for patients to acclimate to potential side effects of tirasemtiv to potentially reduce the rate of early termination on study medication post randomization as compared to BENEFIT-ALS. In addition, VITALITY-ALS randomizes patients to three different target dose levels to evaluate the potential effect of dose on the safety, tolerability and efficacy of tirasemtiv. Patients in BENEFIT-ALS were randomized to one target dose level of 500 mg/day and investigators were encouraged to up-titrate patients to their maximally tolerated dose levels. In addition, in VITALITY-ALS, patients are up-titrated more slowly (two weeks at each dose level before up-titration in VITALITY-ALS versus one week in BENEFIT-ALS). We believe these and other design changes in VITALITY-ALS may decrease the rate of early terminations on tirasemtiv after randomization compared to the rate we observed after randomization in BENEFIT-ALS.

In January 2016, we amended the protocol of VITALITY-ALS to provide for an increase in the number of patients to be enrolled in the clinical trial from approximately 445 patients to approximately 600 patients. Increasing the number of patients enrolled in VITALITY-ALS will increase the statistical power to detect a difference in the primary efficacy endpoint (change from baseline in SVC at 24 weeks) between tirasemtiv and placebo.

In July 2015, we were awarded a $1.5 million grant from The ALS Association (the ALSA Grant) to support the conduct of VITALITY-ALS as well as the collection of clinical data and plasma samples from patients in VITALITY-ALS in order to help advance the discovery of potentially useful biomarkers in ALS. The grant provides funding for collaboration among Cytokinetics, The ALS Association and the Barrow Neurological Institute to enable plasma samples collected from patients enrolled in VITALITY-ALS to be added to The Northeastern ALS Consortium (NEALS) Repository, a resource for the academic research community to identify biomarkers that may help to assess disease progression and underlying disease mechanisms in ALS. In 2015, Cytokinetics achieved its first milestone under the ALSA Grant which triggered a payment of $0.5 million in accordance with the ALSA Grant. We recorded $0.1 million as grant revenue as qualified expenses were incurred and approved by management.

In August 2016, we announced the completion of patient enrollment in VITALITY-ALS. We convened the second Data Monitoring Committee Meeting for VITALITY-ALS to review unblinded safety and efficacy data; and the Committee recommended continuing the trial without modifications to the protocol.

In October 2016, we initiated VIGOR-ALS (**V**entilatory **I**nvestigations in **G**lobal **O**pen-Label **R**esearch in **ALS**), an open-label extension clinical trial designed to assess the long-term safety and tolerability of tirasemtiv, in patients with ALS who have completed their participation in VITALITY-ALS. VIGOR-ALS will provide supplemental data on the effects of the long-term use of tirasemtiv.

Prior Clinical Experience with Tirasemtiv

BENEFIT-ALS: In 2012, we initiated BENEFIT-ALS, a Phase 2b, multi-national, double-blind, randomized, placebo-controlled, clinical trial designed to evaluate the safety, tolerability and efficacy of tirasemtiv in patients with ALS.

In 2014, BENEFIT-ALS results were presented at the 66th Annual Meeting of the American Academy of Neurology. BENEFIT-ALS did not achieve its primary efficacy endpoint, the mean change from baseline in the ALS Functional Rating Scale in its revised form (ALSFRS-R; $p = 0.11$). Treatment with tirasemtiv resulted in a statistically significant and potentially clinically meaningful reduction in the decline of slow vital capacity (SVC), a measure of the strength of the skeletal muscles responsible for breathing. SVC has been shown to be an important predictor of disease progression and survival in prior trials of patients with ALS. At week 12, the decline in SVC from baseline was -3.12 for patients receiving tirasemtiv versus -8.66 for those receiving placebo ($p < 0.0001$). From week 0 to week 12, the

slope of decline in SVC measured as percentage points per day was -0.0394 for patients receiving tirasemtiv versus -0.0905 for those receiving placebo (p = 0.0006).

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The analyses of other pre-specified secondary efficacy endpoints in BENEFIT-ALS produced mixed results. The muscle strength mega-score, a measure of strength combining the data from several muscle groups in each patient, declined more slowly on tirasemtiv versus placebo. The difference in the rate of decline for sniff nasal inspiratory pressure (SNIP) was not statistically significant); however, SNIP decreased more on tirasemtiv compared with placebo in a statistically significant manner at 4 and 12 weeks. No differences in maximum voluntary ventilation and hand grip fatigue were observed on tirasemtiv versus placebo.

Serious adverse events (SAEs) during double-blind treatment were more frequent on tirasemtiv than on placebo (9.0% vs. 5.4%). The most common SAE was respiratory failure which occurred in 1 patient on tirasemtiv and 3 patients on placebo. Confusional state and delirium occurred in 2 patients on tirasemtiv and no patients on placebo. More patients on tirasemtiv withdrew from the trial following randomization than on placebo (99 vs. 33 patients, respectively). Adverse events more common on tirasemtiv than on placebo (>10% difference) were dizziness, fatigue, and nausea.

Tirasemtiv Presentations and Publications

In January 2016, in collaboration with Knopp Biosciences, we presented exploratory analyses of data from patients with ALS combined from three different sources: First, the placebo data from EMPOWER, the Phase 3 clinical trial of Knopp s dexpramipexole in patients with ALS, second, the placebo data from Cytokinetics Phase 2b study of tirasemtiv in patients with ALS, BENEFIT-ALS, and finally, Pooled Resource Open-Access ALS Clinical Trials (PRO-ACT) database. These combined databases included multiple observations of SVC over time from over 900 patients with ALS. Our analyses of this combined database demonstrated that the rate of decline of SVC predicts the risk of meaningful clinical events, including a decline in any one of the three respiratory questions of the ALSFRS-R, as well as the time to the first occurrence of respiratory insufficiency, tracheostomy or death.

In March 2016, we announced a research collaboration with Origent Data Sciences, Inc. (Origent) to refine and prospectively validate an Origent computer model to predict the course of ALS disease progression leveraging placebo data from Cytokinetics clinical trials of tirasemtiv and data from other ALS trials in the PRO-ACT database. Funded by Origent s receipt of a grant from The ALS Association, this joint research program will enable the first prospective validation of the predictive model in a clinical trial setting. The data presented showed that FVC measurements could be used to predict SVC values of ALS patients using a machine-based learning technique. Previously, the Origent models predicting both function and survival of ALS patients have been validated using their internal and retrospective external datasets.

Also in March 2016, the results of BENEFIT-ALS were published in a manuscript titled, A randomized, placebo-controlled, double-blind phase IIb trial evaluating the safety and efficacy of tirasemtiv in patients with amyotrophic lateral sclerosis, in the Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration journal. Results from this trial were first presented at the Annual Meeting of the American Academy of Neurology in 2014.

Tirasemtiv Strategic and Commercial Planning

In 2016, we continued preparing for the potential commercialization of tirasemtiv in North America and Europe. These activities included interactions with manufacturers, and corporate development and commercial planning activities to support various scenarios. We expect to continue to engage extensively with ALS experts, both neuromuscular and pulmonary, and with payors, regulatory authorities and patient advocacy groups as we develop plans for the potential commercialization of tirasemtiv as a treatment for patients living with ALS. These commercialization plans will include market assessment and corporate development activities to support the launch of tirasemtiv in North America and Europe, if appropriate.

Background on ALS Market. Limited options exist for the treatment of patients with ALS, which affects as many as 30,000 Americans, with an estimated 5,600 new cases diagnosed each year in the U.S. Based on our

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primary market research, the per capita prevalence and incidence appears similar in the major European markets. ALS is 20% more common in men than women; however, with increasing age, the prevalence becomes more equal between men and women. The life expectancy of an ALS patient averages two to five years from the time of diagnosis, mostly due to respiratory issues. Of the patients diagnosed with ALS, 5 to 10% have a family history of the disease (familial ALS) and remaining 90 to 95% have the sporadic form. The majority of patients with ALS in the U.S. and Europe receive treatment at a concentrated number of multidisciplinary centers that specialize in the unique needs of these patients. In the U.S., there are approximately 156 ALS multidisciplinary clinics, according to either the ALS Association or the Muscular Dystrophy Association. For most patients with ALS, death is usually due to respiratory failure because of diminished strength in the skeletal muscles responsible for breathing. We believe that there is a need for novel therapies to address the urgent unmet medical issues of this patient population which could be addressed by a small, targeted sales force. If tirasemtiv is approved by regulatory authorities in the U.S. or Europe for commercialization for ALS, we believe that we may be able to independently commercialize tirasemtiv in these concentrated markets.

CK-2127107 and Other Skeletal Muscle Activators

Astellas Strategic Alliance

CK-2127107, a next-generation fast skeletal troponin activator, is being developed jointly by Cytokinetics and Astellas. In 2013, we formed a collaboration with Astellas with the primary objective of advancing novel therapies for diseases and medical conditions associated with muscle impairment and weakness. Under the collaboration, we exclusively licensed to Astellas rights to co-develop and potentially co-commercialize CK-2127107 in non-neuromuscular indications. In 2014, we and Astellas agreed to expand the collaboration to include certain neuromuscular indications, including SMA, and to advance CK-2127107 into Phase 2 clinical development, initially in SMA. In connection with the expanded collaboration, we and Astellas agreed to extend the joint research program through 2016. In 2016, Cytokinetics and Astellas further amended the collaboration agreement to expand our collaboration to include the development of CK-2127107 for the potential treatment of ALS, as well as the possible development in ALS of other fast skeletal regulatory activators previously licensed by us to Astellas. The 2016 Astellas Amendment became effective in September 2016. The 2016 Astellas Amendment also extends the existing joint research program focused on the discovery of additional next-generation skeletal muscle activators through 2017, and includes sponsored research at Cytokinetics. Finally, under the 2016 Astellas Amendment, we granted Astellas the Option on Tirasemtiv, as described above.

Addition of ALS as an Added Indication (CK-2127107 and other fast skeletal activators)

In connection with the execution of the 2016 Astellas Amendment, we received a non-refundable upfront amendment fee of $35 million. In addition, we received an accelerated $15 million milestone payment that would have been payable upon the initiation of the first Phase 2 clinical trial of CK-2127107 as the lead compound in ALS, as if such milestone had been achieved upon the execution of the 2016 Astellas Amendment.

We and Astellas are collaborating to develop CK-2127107 in ALS. Astellas is primarily responsible for the development of CK-2127107 in ALS, but we will conduct the Phase 2 clinical trial of CK-2127107 in ALS and will share in the operational responsibility for later clinical trials. Subject to specified guiding principles, decision making will be by consensus, subject to escalation and, if necessary, Astellas final decision making authority on the development (including regulatory affairs), manufacturing, medical affairs and commercialization of CK-2127107 and other fast skeletal regulatory activators in ALS. We and Astellas share equally the costs of developing CK-2127107 in ALS for potential registration and marketing authorization in the U.S. and Europe, provided that (i) Astellas has agreed to solely fund Phase 2 development costs of CK-2127107 in ALS subject to a right to recoup our share of such

costs plus a 100% premium by reducing future milestone and royalty payments to us and (ii) we may defer (but not eliminate) a portion of our co-funding obligation for development activities after Phase 2 for up to 18 months, subject to certain conditions. We have the right to co-fund our share of such Phase 2 development costs on a current basis, in which case there would not be a premium due to

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Astellas. Cytokinetics will also receive approximately $41.8 million in additional sponsored research and development funding through 2018 which includes Astellas funding of Cytokinetics conduct of the Phase 2 clinical development of CK-2127107 in ALS (approximately $36.6 million) as well as the continuing research collaboration (approximately $5.2 million).

Based on the achievement of pre-specified criteria, Cytokinetics may receive over $600.0 million in milestone payments relating to the development and commercial launch of collaboration products, including up to $112.0 million (of which Cytokinetics has now received $17.0 million) relating to early development of CK-2127107 and for later-stage development and commercial launch milestones for CK-2127107 in non-neuromuscular indications, and over $100.0 million in development and commercial launch milestones for CK-2127107 in each of SMA and other neuromuscular indications. Cytokinetics may also receive up to $200.0 million in payments for achievement of pre-specified sales milestones related to net sales of all collaboration products under the Current Astellas Agreement. If Astellas commercializes any collaboration products, we will also receive royalties on sales of such collaboration products, including royalties ranging from the high single digits to the high teens on sales of products containing CK-2127107. We can co-fund certain development costs for CK-2127107 and other compounds in exchange for increased milestone payments and royalties; such royalties may increase under certain scenarios to exceed twenty percent. In addition to the foregoing development, commercial launch and sales milestones, Cytokinetics may also receive payments for the achievement of pre-specified milestones relating to the joint research program.

Cytokinetics retains an option to conduct early-stage development for certain agreed indications at its initial expense, subject to reimbursement if development continues under the collaboration. Cytokinetics also retains an option to co-promote collaboration products containing fast skeletal troponin activators for neuromuscular indications in the U.S., Canada and Europe, in addition to its option to co-promote other collaboration products in the U.S. and Canada. Astellas will reimburse Cytokinetics for certain expenses associated with its co-promotion activities.

In December 2014, we and Astellas entered into the 2014 Astellas Agreement pursuant to which we received a non-refundable upfront payment of $30.0 million. Concurrently, we entered into a common stock purchase agreement with Astellas, which provided for the sale of 2,040,816 shares of our common stock to Astellas at a price per share of $4.90 and an aggregate purchase price of $10.0 million. Pursuant to this agreement, Astellas agreed to certain trading and other restrictions with respect to our common stock. Concurrently, Cytokinetics earned a $15.0 million milestone payment relating to Astellas decision to advance CK-2127107 into Phase 2 clinical development. Cytokinetics was also eligible to potentially receive over $20.0 million in reimbursement of sponsored research and development activities during the two years of the collaboration following the execution of the 2014 Astellas Agreement.

CK-2127107 Clinical Development

SMA Clinical Development: Cytokinetics in collaboration with Astellas is conducting a Phase 2 clinical development program. Cytokinetics started a Phase 2 clinical trial of CK-2127107 in patients with SMA (CY 5021) in December 2015. The clinical trial is designed to assess effects of CK-2127107 on multiple measures of muscle function in both ambulatory and non-ambulatory patients with SMA, a severe, genetic neuromuscular disease that leads to debilitating muscle wasting and progressive, often fatal, muscle weakness. The primary objective of this double-blind, randomized, placebo-controlled clinical trial is to determine the potential pharmacodynamic effects of a suspension formulation of CK-2127107 following multiple oral doses in patients with Type II, Type III, or Type IV SMA. Secondary objectives are to evaluate the safety, tolerability and pharmacokinetics of CK-2127107. The trial will enroll seventy-two patients in two sequential, ascending dose cohorts (two cohorts of 36 patients each, stratified half ambulatory and half non-ambulatory).

The first cohort of patients received 150 mg of CK-2127107 dosed twice daily for eight weeks; the second cohort of patients will receive 450 mg of CK-2127107 dosed twice daily or a lower dose, depending on the data

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from the first cohort. At the conclusion of the trial, approximately 24 patients will have been randomized to placebo, approximately 24 patients to 150 mg of CK-2127107 twice daily and approximately 24 patients to 450 mg of CK-2127107 twice daily (or a lower dose, pending the review of data from the first cohort). In each of these three treatment groups of approximately 24 patients each, roughly half will be ambulatory and half will be non-ambulatory. Multiple assessments of skeletal muscle function and fatigability will be performed including respiratory assessments, upper limb strength and functionality for non-ambulatory patients, as well as six-minute walk and timed-up-and-go for ambulatory patients.

We continue enrollment patients with SMA in this Phase 2 clinical trial, in collaboration with Astellas. We anticipate that the trial will complete enrollment and report data in the second half of 2017.

COPD Clinical Development: In June 2016, Astellas, in collaboration with Cytokinetics, started a Phase 2 clinical trial of CK-2127107 in patients with COPD. Astellas is conducting this randomized, double-blind, placebo controlled two period crossover clinical trial designed to assess the effect of CK-2127107 on physical function in patients with COPD. The trial is expected to enroll approximately 40 patients in the United States and is designed to assess the effect of CK-2127107 compared to placebo on exercise tolerance. Additionally, the trial will assess the cardiopulmonary and neuromuscular effect of CK-2127107 relative to placebo and the effect of CK-2127107 on resting spirometry relative to placebo. The safety, tolerability and pharmacokinetics of CK-2127107 also will be assessed. We expect Astellas to continue enrollment in this Phase 2 clinical trial of CK-2127107 in patients with COPD in 2017.

ALS Clinical Development: We anticipate that we will begin a Phase 2 clinical trial of CK-2127107 in patients with ALS mid-2017.

Frailty Clinical Development: We anticipate that Astellas will begin a Phase 1b clinical trial of CK-2127107 in elderly patients with limited mobility in the first half of 2017.

Prior Clinical Experience with CK-2127107

We completed five Phase 1 clinical trials evaluating safety, tolerability and pharmacokinetics and pharmacodynamics of CK-2127107 in both oral tablet and liquid suspension formulations in healthy volunteers. The Phase 1 clinical trials demonstrated that CK-2127107 appeared well-tolerated in healthy volunteers and that exposures generally increased across the dose ranges studied. CK-2127107 increased the response of muscle to neuromuscular input in a dose and plasma concentration related fashion in healthy volunteers consistent with preclinical observations.

CK-2127107 Commercial Market

Background on SMA Market: Spinal muscular atrophy (SMA) is a severe neuromuscular disease that occurs in 1 in every 6,000 to 10,000 live births each year resulting in a prevalence of 10,000 to 25,000 patients in the U.S., and is one of the most common fatal genetic disorders. SMA manifests in various degrees of severity as progressive muscle weakness resulting in respiratory and mobility impairment. There are four types of SMA, distinguished by the time of the initial onset of muscle weakness and the severity of related symptoms: Type I (severe), Type II (intermediate), Type III (juvenile) and Type IV (adult onset). Life expectancy and disease severity varies by type of SMA from Type I, who have the worst prognosis and a life expectancy of approximately two years from birth, to Type IV, who have a normal life span but with gradual weakness in the proximal muscles of the extremities resulting in mobility issues. Type II, III and IV patients are often characterized by their ambulatory status as it is an important driver of clinical decisions and care, and constitute 50% of the incident patient population but as much as 90% of the prevalent patient population. Few treatment options exist for these patients, resulting in a high unmet need for new therapeutic options

to ameliorate symptoms, improve muscle function and modify disease progression.

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Ongoing Research in Skeletal Muscle Activators

Our research on the direct activation of skeletal muscle continues in two areas. We are conducting translational research in preclinical models of disease and muscle function with fast skeletal troponin activators to explore the potential clinical applications of this novel mechanism in diseases or conditions associated with skeletal muscle dysfunction. We also intend to conduct preclinical research on other chemically and pharmacologically distinct mechanisms to activate the skeletal sarcomere.

We advanced a next-generation skeletal muscle activator into IND-enabling studies in 2016 and earned a $2.0 million milestone payment. We are conducting a joint research program with Astellas directed to the discovery of next-generation skeletal muscle activators. Under the 2016 Astellas Amendment, the joint research program will continue through 2017 and Astellas will reimburse us for certain research activities we perform.

Cardiac Muscle Contractility Program

Overview

Our cardiac muscle contractility program is focused on the cardiac sarcomere, the basic unit of muscle contraction in the heart. The cardiac sarcomere is a highly ordered cytoskeletal structure composed of cardiac muscle myosin, actin and a set of regulatory proteins. This program is currently directed towards the discovery and development of small molecule cardiac muscle myosin activators with the goal of developing novel drugs to treat acute and chronic heart failure. Cardiac muscle myosin is the cytoskeletal motor protein in the cardiac muscle cell. It is directly responsible for converting chemical energy into the mechanical force, resulting in cardiac muscle contraction. This program is based on the hypothesis that activators of cardiac muscle myosin may address certain adverse properties of existing positive inotropic agents. Current positive inotropic agents, such as beta-adrenergic receptor agonists or inhibitors of phosphodiesterase activity, increase the concentration of intracellular calcium, thereby increasing cardiac sarcomere contractility. The effect on calcium levels, however, also has been linked to potentially life-threatening side effects. In contrast, our novel cardiac muscle myosin activators work by a mechanism that directly stimulates the activity of the cardiac muscle myosin motor protein, without increasing the intracellular calcium concentration. They accelerate the rate-limiting step of the myosin enzymatic cycle and shift it in favor of the force-producing state. Rather than increasing the velocity of cardiac contraction, this mechanism instead lengthens the systolic ejection time, which results in increased cardiac function in a potentially more oxygen-efficient manner.

Amgen Strategic Alliance.

In December 2006, we entered into a collaboration and option agreement with Amgen to discover, develop and commercialize novel small molecule therapeutics, including omecamtiv mecarbil, that activate cardiac muscle contractility for potential applications in the treatment of heart failure (the Amgen Agreement). The agreement granted Amgen an option to obtain an exclusive license worldwide, except Japan, to develop and commercialize omecamtiv mecarbil and other drug candidates arising from the collaboration. In May 2009, Amgen exercised its option. As a result, Amgen became responsible for the development and commercialization of omecamtiv mecarbil and related compounds at its expense worldwide (excluding Japan), subject to our development and commercialization participation rights. Amgen reimburses us for certain research and development activities we perform under the collaboration.

In June 2013, Cytokinetics and Amgen executed an amendment to the Amgen Agreement to include Japan, resulting in a worldwide collaboration (the Amgen Agreement Amendment). Under the terms of the Amgen Agreement Amendment, we received a non-refundable upfront license fee of $15.0 million in June 2013. Under the Amgen

Agreement Amendment, we conducted a Phase 1 pharmacokinetic study intended to support inclusion of Japan in a potential Phase 3 clinical development program and potential global registration dossier for omecamtiv mecarbil. Amgen reimbursed us for the costs of this study. In addition, we are eligible to receive additional pre-commercialization milestone payments relating to the development of omecamtiv mecarbil in

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Japan of up to $50.0 million, and royalties on sales of omecamtiv mecarbil in Japan. In conjunction with the Amgen Agreement Amendment, we also entered into a common stock purchase agreement which provided for the sale of 1,404,100 shares of our common stock to Amgen at a price per share of $7.12 and an aggregate purchase price of $10.0 million which was received in June 2013. Pursuant to this agreement, Amgen agreed to certain trading and other restrictions with respect to our common stock.

Under the Amgen Agreement as amended we are eligible for potential additional pre-commercialization and commercialization milestone payments of over $600.0 million in the aggregate on omecamtiv mecarbil and other potential products arising from research under the collaboration, and royalties that escalate based on increasing levels of annual net sales of products commercialized under the agreement. The Amgen Agreement also provides for us to receive increased royalties by co-funding Phase 3 development costs of omecamtiv mecarbil and other drug candidates under the collaboration. In February 2017, we agreed to exercise our option to co-invest $40.0 million in the Phase 3 development program of omecamtiv mecarbil. As a result, we are eligible to receive an incremental royalty of up to 4% on increasing worldwide sales of omecamtiv mecarbil outside of Japan. Exercising and fully co-funding our option will afford us the right to co-promote omecamtiv mecarbil in institutional care settings in North America, with reimbursement by Amgen for certain sales force activities.

In July 2013, Amgen announced that it had granted an option to commercialize omecamtiv mecarbil in Europe to Servier, with Cytokinetics consent, pursuant to an Option, License and Collaboration Agreement (the Servier Agreement).

In August 2016, we entered into a Letter Agreement with Amgen and Servier (the Letter Agreement), which (i) expands the territory of the sublicense to Servier to include specified countries in the CIS, including Russia and (ii) provides that, if Amgen s rights under the Amgen Agreement, as amended, are terminated with respect to the territory of such sublicense, the sublicensed rights previously granted by Amgen to Servier under the Servier Agreement will remain in effect and become a direct license or sublicense of such rights by us to Servier, on substantially the same terms as set forth in the Servier Agreement, including but not limited to Servier s payment of its share of agreed development costs and future milestone and royalty payments to us. The Letter Agreement does not otherwise modify our rights and obligations under the Amgen Agreement, as amended, or create any additional financial obligations of Cytokinetics, unless we otherwise agree in writing.

In September 2016, Amgen and Servier announced Servier s decision to exercise its option to commercialize omecamtiv mecarbil in Europe as well as the CIS, including Russia. The option and related commercialization sublicense to Servier is subject to the terms and conditions of the Amgen Agreement. Amgen remains responsible for the performance of its obligations under the Amgen Agreement, as amended, relating to Europe and the CIS, including the payment of milestones and royalties relating to the development and commercialization of omecamtiv mecarbil in Europe and the CIS.

Omecamtiv Mecarbil

Our lead drug candidate from this program is omecamtiv mecarbil, a novel cardiac muscle myosin activator. We expect omecamtiv mecarbil to be developed as a potential treatment across the continuum of care in heart failure both for use in the hospital setting and for use in the outpatient setting.

Omecamtiv Mecarbil Clinical Development

GALACTIC-HF is a Phase 3 cardiovascular outcomes clinical trial of omecamtiv mecarbil which is being conducted by Amgen, in collaboration with Cytokinetics. Coincident with the start of the trial, Amgen made a $26.7 million

milestone payment to Cytokinetics. The primary objective of this double-blind, randomized, placebo-controlled multicenter clinical trial is to determine if treatment with omecamtiv mecarbil when added to standard of care is superior to standard of care plus placebo in reducing the risk of cardiovascular death or heart failure events in patients with high risk chronic heart failure and reduced ejection fraction. GALACTIC-HF is

being conducted under a Special Protocol Assessment (SPA) with the U.S. FDA. GALACTIC-HF is planned to enroll approximately 8,000 symptomatic chronic heart failure patients in over 900 sites in 35 countries who are either currently hospitalized for a primary reason of heart failure or have had a hospitalization or admission to an emergency room for heart failure within one year prior to screening. In order to be eligible to participate in GALACTIC-HF patients should have an LVEF £ 35%, be NYHA class II to IV, and have an elevated BNP or NT-proBNP. Patients will be randomized to either placebo or omecamtiv mecarbil with dose titration up to a maximum dose of 50 mg twice daily based on the plasma concentration of omecamtiv mecarbil after initiation of drug therapy. The primary endpoint is a composite of time to cardiovascular death or first heart failure event, which is defined as either a hospitalization for heart failure or other urgent treatment for worsening heart failure. Secondary endpoints include time to cardiovascular death; patient reported outcomes as measured by the Kansas City Cardiomyopathy Questionnaire Total Symptom Score; time to first heart failure hospitalization; and all-cause death.

Cytokinetics and Amgen are also planning a potential exercise performance/cardiac function clinical trial to be conducted by Cytokinetics. Amgen will be responsible for reimbursing us for the out-of-pocket development costs associated with this clinical trial.

In April 2016, we announced the start of a Phase 2 clinical trial of omecamtiv mecarbil in Japanese subjects with chronic heart failure and reduced ejection fraction and we expect data from this trial in Q3 2017.

Prior Clinical Experience with Omecamtiv Mecarbil

COSMIC-HF. COSMIC-HF is a Phase 2, double-blind, randomized, placebo-controlled, multicenter, clinical trial designed to assess the pharmacokinetics and tolerability of omecamtiv mecarbil dosed orally in patients with heart failure and left ventricular systolic dysfunction as well as its effects on echocardiographic measures of cardiac function. COSMIC-HF was conducted by Amgen in collaboration with Cytokinetics. The study began with two dose escalation cohorts of 40 patients each, randomized 1:1:1:1 to placebo or one of three different modified release oral formulations of omecamtiv mecarbil for seven days. The omecamtiv mecarbil dose in the first of these two dose escalation cohorts was 25 mg twice daily; in the second, it was 50 mg twice daily. The purpose of the dose escalation cohorts was to select one of the three modified release oral formulations of omecamtiv mecarbil for further evaluation in a larger group of patients treated for a longer period of time.

The expansion phase of COSMIC-HF was designed to evaluate the pharmacokinetics, pharmacodynamics, safety and tolerability of the modified release oral formulation omecamtiv mecarbil selected based on the results of the two dose escalation cohorts in 448 patients with chronic heart failure and left ventricular systolic dysfunction. Patients were randomized 1:1:1 to receive either placebo or treatment with omecamtiv mecarbil 25 mg twice daily or a dose titration group where 25 mg twice daily dosing could be increased to 50 mg twice daily depending on plasma concentrations of omecamtiv mecarbil after two weeks of treatment with the 25 mg dose.

In November 2015, we announced the results from the expansion phase of COSMIC-HF (Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure) that were presented at the American Heart Association Scientific Sessions 2015 in Orlando, Florida. Data from the expansion phase showed that dose titration controlled patient exposure to omecamtiv mecarbil. Approximately 60 percent of patients in the dose titration group escalated dosing to 50 mg twice daily. The study met its primary pharmacokinetics objective.

Following 20 weeks of treatment, statistically significant improvements were observed in pre-specified secondary endpoint measures of cardiac function in the dose titration group, compared to placebo. Systolic ejection time increased by 25.0 msec (p<0.001), stroke volume increased by 3.63 mL (p=0.022) and heart rate decreased by 2.97 beats per min (p=0.007). Left ventricular end-systolic and end-diastolic dimensions decreased by 1.79 mm (p=0.003)

and 1.29 mm (p=0.013), respectively, and were associated with statistically significant reductions in left ventricular end-systolic and end-diastolic volumes. N-terminal pro-brain natriuretic peptide (NT-proBNP) decreased by 970 pg/mL (p=0.007). Additionally, in the 25 mg twice daily group, there were

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statistically significant increases in systolic ejection time and stroke volume and a decrease in NT-proBNP. All changes are from baseline compared to placebo. The pharmacodynamic effects of omecamtiv mecarbil were generally dose dependent and larger in patients that received oral dosing with 50 mg twice daily.

Adverse events (AEs), including serious AEs, in patients on omecamtiv mecarbil were comparable to placebo. The incidence of adjudicated deaths (2.7 percent died on placebo, 1.4 percent died on omecamtiv mecarbil), myocardial infarction (1.34 percent on placebo, 0.34 percent on omecamtiv mecarbil) and unstable angina (0 percent on placebo, 0.34 percent on omecamtiv mecarbil) was similar. Other cardiac AEs were generally balanced between placebo and active treatment groups. In the omecamtiv mecarbil groups, compared to placebo, cardiac troponin increased by 0.001 ng/mL and 0.006 ng/mL (median change from baseline at week 20) in the 25 mg twice daily group and dose titration group, respectively. Events of increased troponin (n=278 across all treatment groups) were independently adjudicated and none were determined to be myocardial ischemia or infarction.

ATOMIC-AHF. ATOMIC-AHF (Acute Treatment with Omecamtiv Mecarbil to Increase Contractility in Acute Heart Failure) was an international, randomized, double-blind, placebo-controlled, Phase 2b clinical trial of intravenous omecamtiv mecarbil in patients with left ventricular systolic dysfunction hospitalized with acutely decompensated heart failure, completed in 2013. The primary efficacy endpoint of dyspnea symptom response was not met; however, the study demonstrated favorable trends between the dose and plasma concentration of omecamtiv mecarbil and dyspnea response. Rates of adverse events (AEs), serious AEs, adjudicated deaths and hospitalizations were similar between omecamtiv mecarbil and placebo groups. Omecamtiv mecarbil was not associated with an increased incidence of tachyarrhythmias nor were heart rate or blood pressure adversely affected.

Nine Phase 1 clinical trials of omecamtiv mecarbil have been conducted in healthy subjects: five conducted by Cytokinetics and four conducted by Amgen in collaboration with Cytokinetics. Cytokinetics has also conducted two Phase 2a clinical trials of omecamtiv mecarbil. These clinical trials were designed to evaluate the safety, tolerability, pharmacodynamic and pharmacokinetic profiles of both intravenous and oral formulations in a diversity of patients, including patients with stable heart failure and patients with ischemic cardiomyopathy. In these trials, omecamtiv mecarbil exhibited generally linear, dose-proportional pharmacokinetics across the dose ranges studied. The adverse effects observed at intolerable doses in humans appeared similar to the adverse findings which occurred in preclinical safety studies at similar plasma concentrations. These effects are believed to be related to the mechanism of action of this drug candidate which, at intolerable doses, resulted in an excessive prolongation of the systolic ejection time (i.e., the time in which the heart is contracting). However, these effects resolved promptly with discontinuation of the infusions of omecamtiv mecarbil.

Ongoing Research in Cardiac Muscle Contractility.

We continued our joint research program with Amgen directed to next-generation compounds in our cardiac muscle contractility program in 2016. We expect to continue our joint research program with Amgen in 2017. Under the Amgen Agreement, Amgen reimburses us for certain research activities we perform.

Presentations and Publications

In March 2016, the manuscript, Acute Treatment with Omecamtiv Mecarbil to Increase Contractility in Acute Heart Failure, The ATOMIC-AHF Study, was published in the Journal of the American College of Cardiology. Results from this trial were first presented at the European Society of Cardiology Meeting in 2013.

In September 2016, additional results from COSMIC-HF were presented in a Rapid Fire Abstract Session at the Heart Failure Society of America Scientific Meeting in Orlando, Florida. The results showed that omecamtiv mecarbil may

improve symptoms in patients with moderate to severe heart failure symptoms versus placebo after 20 weeks of double-blind treatment, as measured by the Kansas City Cardiomyopathy Questionnaire Total

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Symptom Score (TSS), one of the sub-domains of a self-administered questionnaire that measures quality-of-life in patients with heart failure. At week 20, the TSS was increased (with increases in the score reflecting improvement) in a dose-related fashion, with a 4.9 point improvement in the PK-guided dose titration group (p=0.03). This improvement was greater among patients who were moderately to severely symptomatic at baseline, with the largest magnitude in the PK-guided dose titration treatment group (6.5, p=0.09). Patients who were asymptomatic or mildly symptomatic had modest improvements in the TSS.

In November 2016, the results from COSMIC-HF were published in The Lancet. Results from this trials were first presented at a Late-Breaking Clinical Trial session at the American Heart Association (AHA) Scientific Sessions in 2015.

Omecamtiv Mecarbil Heart Failure Market

Background on Heart Failure Market. Heart failure is a widespread and debilitating syndrome affecting millions of people in the United States. The high and rapidly growing prevalence of heart failure translates into significant hospitalization rates and associated societal costs. About 6.4 million people in the United States have heart failure, resulting in nearly one million hospital discharges with the primary diagnosis of heart failure and approximately 300,000 deaths each year. For people over 65 years of age, heart failure incidences approach 10 per 1000 and approximately 50% of people diagnosed with heart failure will die within 5 years of diagnosis. These numbers are increasing due to the aging of the U.S. population and an increased likelihood of survival following acute myocardial infarctions. The costs to society attributable to the prevalence of heart failure are high, especially as many chronic heart failure patients suffer repeated acute episodes. Despite currently available therapies, readmission rates for heart failure patients remain high. In general, the mortality following hospitalization for patients with heart failure is 10.4% at 30 days, 22% at one year and 42.3% at 5 years, despite the availability of therapeutic alternatives for treatment of these patients. These poor outcomes in the setting of current therapies points to the need for novel therapeutics that may offer further reductions in morbidity and mortality. The annual cost of heart failure to the U.S. health care system is estimated to be $32 billion and is predicted to grow 120% to almost $70 billion by the year 2030. Today, a portion of that cost is attributable to drugs used to treat each of chronic and acute heart failure. Approximately 70% of those costs are due to hospitalization, home health and physician care. In the U.S., Medicare is one of the largest payors for heart failure related costs. Approximately 50% of Medicare beneficiaries with heart failure are concentrated in the top 20% of the hospital referral regions in the U.S. New drug therapies that could reduce the number of hospitalizations could decrease the cost to the health care system.

Beyond Muscle Contractility

We developed preclinical expertise in the mechanics of skeletal, cardiac and smooth muscle that extends from proteins to tissues to intact animal models. Our translational research in muscle contractility has enabled us to better understand the potential impact of small molecule compounds that increase skeletal or cardiac muscle contractility and to apply those findings to the further evaluation of our drug candidates in clinical populations. In addition to contractility, other major functions of muscle play a role in certain diseases that could benefit from novel mechanism treatments. Accordingly, our knowledge of muscle contractility may serve as an entry point to the discovery of novel treatments for disorders involving muscle functions other than muscle contractility. We are leveraging our current understandings of muscle biology to investigate new ways of modulating these other aspects of muscle function for other potential therapeutic applications.

Intellectual Property

Our policy is to seek patent protection for the technologies, inventions and improvements that we develop that we consider important to the advancement of our business. As of December 31, 2016, we owned or co-owned or licensed 87 issued U.S. patents, over 310 issued patents in various foreign jurisdictions, and over 190 additional pending U.S. and foreign patent applications. We also rely on trade secrets, technical know-how

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and continuing innovation to develop and maintain our competitive position. Our commercial success will depend on obtaining and maintaining patent protection and trade secret protection for our drug candidates and technologies and our successfully defending these patents against third-party challenges. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents cover them or we maintain them as trade secrets.

With regard to our drug candidates directed to muscle biology targets, we have a U.S. patent covering omecamtiv mecarbil and U.S. patents covering our skeletal muscle sarcomere activators including, but not limited to, tirasemtiv and CK-2127107, each of which will expire in 2027, 2027 and 2031, respectively, unless extended or otherwise adjusted. We also have issued patents in various foreign jurisdictions and additional U.S. and foreign patent applications pending for each of our drug candidates. It is not known or determinable whether other patents will issue from any of our other pending applications or what the expiration dates would be for any other patents that do issue.

All of our drug candidates are still in clinical development and have not yet been approved by the FDA. If any of these drug candidates is approved, then pursuant to federal law, we may apply for an extension of the U.S. patent term for one patent covering the approved drug, which could extend the term of the applicable patent by up to a maximum of five additional years.

The degree of future protection of our proprietary rights is uncertain because legal means may not adequately protect our rights or permit us to gain or keep our competitive advantage. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the claim scope of these patents, our ability to enforce our existing patents and to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. The standards that the U.S. Patent and Trademark Office and its foreign counterparts use to grant patents are not always applied predictably or uniformly and are subject to change. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology and pharmaceutical patents. Thus, we cannot be sure that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents do issue, we cannot be sure that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competitive products, or will afford us a commercial advantage over competitive products. For example:

- we or our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;

- we or our licensors might not have been the first to file patent applications for the inventions covered by our pending patent applications and issued patents;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

- some or all of our or our licensors pending patent applications may not result in issued patents or the claims that issue may be narrow in scope and not provide us with competitive advantages;

our and our licensors issued patents may not provide a basis for commercially viable drugs or therapies or may be challenged and invalidated by third parties;

our or our licensors patent applications or patents may be subject to interference, opposition or similar administrative proceedings that may result in a reduction in their scope or their loss altogether;

we may not develop additional proprietary technologies or drug candidates that are patentable; or

the patents of others may prevent us or our partners from discovering, developing or commercializing our drug candidates.

The defense and prosecution of intellectual property infringement suits, interferences, oppositions and related legal and administrative proceedings are costly, time-consuming to pursue and divert resources. The outcome of these types of proceedings is uncertain and could significantly harm our business.

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Our ability to commercialize drugs depends on our ability to use, manufacture and sell those drugs without infringing the patents or other proprietary rights of third parties. U.S. and foreign issued patents and pending patent applications owned by third parties exist that may be relevant to the therapeutic areas and chemical compositions of our drug candidates. While we are aware of certain relevant patents and patent applications owned by third parties, there may be issued patents or pending applications of which we are not aware that could cover our drug candidates. Because patent applications are often not published immediately after filing, there may be currently pending applications, unknown to us, which could later result in issued patents that our activities with our drug candidates could infringe.

The development of our drug candidates and the commercialization of any resulting drugs may be impacted by patents of companies engaged in competitive programs with significantly greater resources. This could result in the expenditure of significant legal fees and management resources.

We also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are often difficult to protect, especially outside of the United States. While we believe that we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, partners and other advisors may unintentionally or willfully disclose our trade secrets to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets would be expensive and time-consuming, and the outcome would be unpredictable. Even if we are able to maintain our trade secrets as confidential, our competitors may independently develop information that is equivalent or similar to our trade secrets.

We seek to protect our intellectual property by requiring our employees, consultants, contractors and other advisors to execute nondisclosure and invention assignment agreements upon commencement of their employment or engagement, through which we seek to protect our intellectual property. Agreements with our employees also preclude them from bringing the proprietary information or materials of third parties to us. We also require confidentiality agreements or material transfer agreements from third parties that receive our confidential information or materials.

For further details on the risks relating to our intellectual property, please see the risk factors under Item 1A of this report, including, but not limited to, the risk factors entitled Our success depends substantially upon our ability to obtain and maintain intellectual property protection relating to our drug candidates and research technologies and If we are sued for infringing third party intellectual property rights, it will be costly and time-consuming, and an unfavorable outcome would have a significant adverse effect on our business.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture, marketing and distribution of drugs. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, labeling, storage, record keeping, approval, advertising and promotion of our drug candidates and drugs.

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act and implementing regulations. The process required by the FDA before our drug candidates may be marketed in the United States generally involves the following:

completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies, all performed in accordance with the FDA s good laboratory practice regulations;

submission to the FDA of an investigational new drug application (IND), which must become effective before clinical trials may begin;

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performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the drug candidate for each proposed indication in accordance with good clinical practices;

submission of a new drug application (NDA) to the FDA, which must usually be accompanied by payment of a substantial user fee;

satisfactory completion of an FDA preapproval inspection of the manufacturing facilities at which the product is produced to assess compliance with current good manufacturing practice (cGMP) regulations and FDA audits of select clinical investigator sites to assess compliance with good clinical practices (GCP); and

FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

Similar regulatory procedures generally apply in countries outside of the United States. This testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our drug candidates will be granted on a timely basis, if at all.

Nonclinical tests include laboratory evaluation of product chemistry, formulation and stability, and studies to evaluate toxicity and pharmacokinetics in animals. The results of nonclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND application to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects may be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND or a foreign equivalent, or those of our collaborators, may not result in authorization from the FDA or its foreign equivalent to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board (IRB) or its foreign equivalent for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the clinical trial until completed. The FDA, the IRB or their foreign equivalents, or the clinical trial sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Clinical Trials. For purposes of an NDA or equivalent submission and approval, clinical trials are typically conducted in the following three sequential phases, which may overlap:

Phase 1: Phase 1 includes the initial introduction of a drug candidate into humans. These studies may be conducted in patients, but are usually conducted in healthy volunteer subjects. These studies are designed to determine the metabolic and pharmacologic actions of the drug candidate in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug candidate s pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 trials.

Phase 2: Phase 2 includes the early controlled clinical studies conducted to obtain some preliminary data on the effectiveness of the drug candidate for a particular indication or indications in patients with the disease or

condition. This phase of testing also helps determine the common short-term side effects and risks associated with the drug candidate. These clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to make an initial determination of potential efficacy of the drug candidate for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. Phase 2a clinical trials generally are designed to study the pharmacokinetic or pharmacodynamic properties and to conduct a preliminary assessment of safety of the drug candidate over a measured dose response range. In some cases, a sponsor may decide to conduct a Phase 2b clinical trial, which is a second, typically larger,

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confirmatory Phase 2 trial that could, if positive and accepted by a regulatory authority, support approval of a drug candidate.

Phase 3: If the Phase 2 clinical trials demonstrate that a dose range of the drug candidate is potentially effective and has an acceptable safety profile, Phase 3 clinical trials are then undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites. Phase 3 trials are also intended to provide an adequate basis for extrapolating the results to the general population and transmitting that information in the drug labeling. Phase 3 studies usually include several hundred to several thousand people, and are usually longer in duration than Phase 2 trials.

At any time during the conduct of a clinical trial, the FDA or a foreign equivalent can impose a clinical hold on the trial if it believes the trial is unsafe or that the protocol is clearly deficient in design in meeting its stated objectives, which requires the conduct of the trial to cease until the clinical hold is removed. In some cases, the FDA or foreign equivalent may condition approval of marketing approval for a drug candidate on the sponsor s agreement to conduct additional clinical trials to further assess the drug s safety and effectiveness after marketing approval, known as Phase 4 clinical trials.

The clinical trials we conduct for our drug candidates, both before and after approval, and the results of those trials, are generally required to be included in a clinical trials registry database that is available and accessible to the public via the internet. A failure by us to properly participate in the clinical trial database registry could subject us to significant civil monetary penalties.

Health care providers in the United States, including research institutions from which we or our partners obtain patient information, are subject to privacy rules under the Health Insurance Portability and Accountability Act of 1996 and state and local privacy laws. In the European Union, these entities are subject to the Directive 95/46-EC of the European Parliament on the protection of individuals with regard to the processing of personal data and individual European Union member states implementing additional legislation. Other countries have similar privacy legislation. We could face substantial penalties if we knowingly receive individually identifiable health information from a health care provider that has not satisfied the applicable privacy laws. In addition, certain privacy laws and genetic testing laws may apply directly to our operations and/or those of our partners and may impose restrictions on the use and dissemination of individuals health information and use of biological samples.

New Drug/Marketing Approval Application. The results of drug candidate development, preclinical testing and clinical trials are submitted to the FDA as part of an NDA. The NDA also must contain extensive manufacturing information. In addition, the FDA may require that a proposed Risk Evaluation and Mitigation Strategy, also known as a REMS, be submitted as part of the NDA if the FDA determines that it is necessary to ensure that the benefits of the drug outweigh its risks. Similar, and in some cases additional, requirements apply in foreign jurisdictions for marketing approval applications for drugs in those jurisdictions. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA often, but not always, follows the advisory committee s recommendations. The FDA may deny approval of an NDA by issuing a complete response letter if the applicable regulatory criteria are not satisfied, or it may require additional clinical data, including data in a pediatric population, or an additional Phase 3 clinical trial or impose other conditions that must be met in order to secure final approval for an NDA.

Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our partners do. Once issued, the FDA or foreign equivalent may withdraw a drug approval if ongoing regulatory

requirements are not met or if safety problems occur after the drug reaches the market. In addition, the FDA or its foreign counterparts may require further testing, including Phase 4 clinical trials, and surveillance or restrictive distribution programs to monitor the effect of approved drugs which have been commercialized. The

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FDA and its foreign counterparts have the power to prevent or limit further marketing of a drug based on the results of these post-marketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to a drug, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain prior FDA approval of a new NDA or NDA supplement, or the foreign equivalent, which may require us to develop additional data or conduct additional preclinical studies and clinical trials.

Satisfaction of FDA regulations and requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years. The actual time required may vary substantially based upon the type, complexity and novelty of the drug candidate or disease. Typically, if a drug candidate is intended to treat a chronic disease, as is the case with some of our drug candidates, safety and efficacy data must be gathered over an extended period of time. Government regulation may delay or prevent marketing of drug candidates for a considerable period of time and impose costly procedures upon our activities. The FDA or any other regulatory agency may not grant approvals for new indications for our drug candidates on a timely basis, if at all. Even if a drug candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages or restrictive distribution programs. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a drug may result in restrictions on the drug or even complete withdrawal of the drug from the market. Delays in obtaining, or failures to obtain, regulatory approvals for any of our drug candidates would harm our business. In addition, we cannot predict what future U.S. or foreign governmental regulations may be implemented.

Orphan Drug Designation. Some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. The FDA grants orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. For example, the FDA has granted tirasemtiv an orphan drug designation for the treatment of ALS. In addition, the European Medicines Agency has granted tirasemtiv orphan medicinal product status for the treatment of ALS.

An FDA orphan drug designation does not shorten the duration of the regulatory review and approval process. If a drug candidate that has an orphan drug designation receives the first FDA marketing approval for the indication for which the designation was granted, then the approved drug is entitled to orphan drug exclusivity. This means that the FDA may not approve another company s application to market the same drug for the same indication for a period of seven years, except in certain circumstances, such as a showing of clinical superiority to the drug with orphan exclusivity or if the holder of the orphan drug designation cannot assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the designation was granted. Competitors may receive approval of different drugs or biologics for the indications for which the orphan drug has exclusivity.

Fast Track Designation. Fast track is a process designed by the FDA to facilitate the development and expedite the review of drugs to treat serious diseases and fill an unmet medical need. Tirasemtiv has been granted fast track designation by the FDA for the treatment of ALS. Although fast track designation does not affect the standards for approval, the benefits of this designation include scheduled meetings to seek FDA input into development plans, the option of submitting an NDA in sections rather than all components simultaneously, and the potential eligibility for priority review if supported by clinical data.

Other Regulatory Requirements. Any drugs manufactured or distributed by us or our partners pursuant to FDA approvals or their foreign counterparts are subject to continuing regulation by the applicable regulatory authority, including recordkeeping requirements and reporting of adverse experiences associated with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and other applicable

regulatory authorities, and are subject to periodic unannounced inspections by these regulatory authorities for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with

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the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA and other regulatory requirements. If our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA or its foreign counterparts may halt our or our partners clinical trials, require us to recall a drug from distribution, or withdraw approval of the NDA for that drug.

For further details on the risks relating to government regulation of our business, please see the risk factors under Item 1A of this report, including, but not limited to, the risk factor entitled The regulatory approval process is expensive, time-consuming and uncertain and may prevent our partners or us from obtaining approvals to commercialize some or all of our drug candidates.

Competition

We compete in the segments of the pharmaceutical, biotechnology and other related markets that address neuromuscular and cardiovascular diseases and other diseases relating to muscle dysfunction, each of which is highly competitive. We face significant competition from most pharmaceutical companies and biotechnology companies that are also researching and selling products designed to address cardiovascular diseases and diseases and medical conditions associated with skeletal muscle weakness and wasting. Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Large pharmaceutical companies in particular have extensive experience in clinical testing and in obtaining regulatory approvals for drugs. These companies also have significantly greater research capabilities than we do. In addition, many universities and private and public research institutes are active in research of neuromuscular and cardiovascular diseases and other diseases where there is muscle dysfunction, some in direct competition with us.

We believe that our ability to successfully compete will depend on, among other things:

- our drug candidates efficacy, safety and tolerability;
- the speed and cost-effectiveness with which we develop our drug candidates;
- the selection of suitable indications for which to develop our drug candidates;
- the successful completion of clinical development and laboratory testing of our drug candidates;
- the timing and scope of any regulatory approvals we or our partners obtain for our drug candidates;
- our or our partners ability to manufacture and sell commercial quantities of our approved drugs to meet market demand;

acceptance of our drugs by physicians and other health care providers;

the willingness of third party payors to provide reimbursement for the use of our drugs;

our ability to protect our intellectual property and avoid infringing the intellectual property of others;

the quality and breadth of our technology;

our employees skills and our ability to recruit and retain skilled employees;

our cash flows under existing and potential future arrangements with licensees, partners and other parties; and

the availability of substantial capital resources to fund development and commercialization activities.

Our competitors may develop drug candidates and market drugs that are less expensive and more effective than our future drugs or that may render our drugs obsolete. Our current or future competitors may also

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commercialize competing drugs before we or our partners can launch any drugs developed from our drug candidates. These organizations also compete with us to attract qualified personnel and potential parties for acquisitions, joint ventures or other strategic alliances.

If tirasemtiv is approved for marketing by the FDA or other regulatory authorities for the treatment of ALS, it may then compete with other potential new therapies for ALS that are currently being developed by companies such as Neuraltus Pharmaceuticals, Inc., Ionis Pharmaceuticals, Inc. (in collaboration with Biogen), Genervon Biopharmaceuticals, LLC, Orion Pharmaceuticals, Orphazyme, Mitsubishi Tanabe Pharma Corporation, Eisai Co., Ltd., Genentech, Inc. Edison Pharma, Q Therapeutics, AB Science, VM Biopharm, Mallinckrodt Pharmaceuticals, Chronos Therapeutics, and MediciNova, Inc. In addition, BrainStorm Cell Therapeutics and Neuralstem, Inc. are each conducting clinical development of stem cell therapies for the potential treatment of ALS. Tirasemtiv may also compete with Riluteck (riluzole), manufactured by Sanofi, Marindale Pharma, and Italfarmaco and several generics manufacturers including Apotex Corp, Glenmark Generics, and Sun Pharmaceuticals.

If CK-2127107 is approved by the FDA or other regulatory authorities for the potential treatment of SMA, potential competitors include Roche (in collaboration with PTC Therapeutics), AveXis, Inc., Pfizer Inc., Ionis Pharmaceuticals, Inc. (in collaboration with Biogen) which is being marketed as Spinraza, Novartis AG, and Bioblast Pharma, Ltd. Drugs that could compete with CK-2127107 could also compete against tirasemtiv in ALS or other neuromuscular diseases, should the appropriate clinical trials be conducted. If CK-2127107 is approved by the FDA for the potential treatment of non-neuromuscular indications associated with muscle weakness, potential competitors include Ligand Pharmaceuticals, Inc., GTx, Inc., Regeneron Pharmaceuticals, Inc. (in collaboration with Sanofi), Eli Lilly & Company, Acceleron Pharma, Stealth Biotherapeutics, Scholar Rock, vTv Therapeutics, Summit Therapeutics, Pfizer Inc., and Novartis (in collaboration with Morphosys AG).

If omecamtiv mecarbil is approved for marketing by the FDA or other regulatory authorities for the treatment of heart failure, it would compete against other drugs used for the treatment of chronic heart failure. These include generic drugs, such as milrinone, dobutamine or digoxin and branded drugs such as Natrecor (nesiritide), Corlanor (ivabradine), and Entresto (LCZ696). Omecamtiv mecarbil could also potentially compete against other novel drug candidates and therapies in development, such as those being developed by ARCA biopharma, Inc., Novartis, Bayer, Capricor Therapeutics, Inc., Cardiorentis AG, Ono Pharmaceutical Company, Juventas Therapeutics, ARMGO Pharma, Inc, Trevena, Inc. in partnership with Forest Laboratories, Inc. (acquired by Allergan, Plc), Stealth Biotherapeutics, Cardioxyl Pharmaceuticals, Inc., Zensun Sci & Tech, Ltd., and Tenax Therapeutics (formerly known as Oxygen Biotherapeutics, Inc.). In addition, there are a number of medical devices both marketed and in development for the potential treatment of heart failure.

Employees

As of December 31, 2016, our workforce consisted of 127 full-time employees, 32 of whom hold Ph.D. or M.D. degrees, or both, and 32 of whom hold other advanced degrees. Of our total full-time employees, 86 are engaged in research and development and 41 are engaged in business and new product development, finance and administration functions

We have no collective bargaining agreements with our employees, and we have not experienced any work stoppages. We believe that our relations with our employees are good.

Investor Information

We file electronically with the SEC our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13 or 15(d) of the Exchange Act. The public may read or copy any materials we file with the SEC at the SEC s Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at

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1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is www.sec.gov.

You may obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to those reports on the day of filing with the SEC on our website at www.cytokinetics.com or by contacting the Investor Relations Department at our corporate offices by calling 650-624-3060. The information found on our website is not part of this or any other report filed with or furnished to the SEC.

Item 1A. ***Risk Factors***

In evaluating our business, you should carefully consider the following risks in addition to the other information in this report. Any of the following risks could materially and adversely affect our business, results of operations, financial condition or your investment in our securities, and many are beyond our control. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also adversely affect our business.

Risks Related To Our Business

We have a history of significant losses and may not achieve or sustain profitability and, as a result, you may lose all or part of your investment.

We have generally incurred operating losses in each year since our inception in 1997, due to costs incurred in connection with our research and development activities and general and administrative costs associated with our operations. Our drug candidates are all in early through late-stage clinical testing, and we and our partners must conduct significant additional clinical trials before we and our partners can seek the regulatory approvals necessary to begin commercial sales of our drugs. We expect to incur increasing losses for at least several more years, as we continue our research activities and conduct development of, and seek regulatory approvals for, our drug candidates, and commercialize any approved drugs. If our drug candidates fail or do not gain regulatory approval, or if our drugs do not achieve market acceptance, we will not be profitable. If we fail to become and remain profitable, or if we are unable to fund our continuing losses, you could lose all or part of your investment.

We will need substantial additional capital in the future to sufficiently fund our operations.

We have consumed substantial amounts of capital to date, and our operating expenditures will increase over the next several years if we expand our research and development activities. We have funded all of our operations and capital expenditures with proceeds from private and public sales of our equity securities, strategic alliances with Amgen, Astellas and others, long term debt, equipment financings, interest on investments, government grants and other grants. We believe that our existing cash and cash equivalents, short-term investments and interest earned on investments should be sufficient to meet our projected operating requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of our drug candidates and other research and development activities, including risks and uncertainties that could impact the rate of progress of our development activities, we are unable to estimate with certainty the amounts of capital outlays and operating expenditures associated with these activities.

For the foreseeable future, our operations will require significant additional funding, in large part due to our research and development expenses and the absence of any revenues from product sales. For example, we will require

significant additional funding to enable us to conduct further development of tirasemtiv for the potential treatment of ALS, including any additional Phase 3 clinical trials that may be required by regulatory authorities

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to receive marketing approval for tirasemtiv. Until we can generate a sufficient amount of product revenue, we expect to raise future capital through strategic alliance and licensing arrangements, public or private equity offerings and debt financings. We do not currently have any commitments for future funding other than reimbursements, milestone and royalty payments that we may receive under our collaboration agreements with Amgen and Astellas. We may not receive any further funds under those agreements. Our ability to raise funds may be adversely impacted by current economic conditions. As a result of these and other factors, we do not know whether additional financing will be available when needed, or that, if available, such financing would be on terms favorable to our stockholders or us.

To the extent that we raise additional funds through strategic alliances or licensing and other arrangements with third parties, we will likely have to relinquish valuable rights to our technologies, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. To the extent that we raise additional funds by issuing equity securities, our stockholders will experience additional dilution and our share price may decline. To the extent that we raise additional funds through debt financing, the financing may involve covenants that restrict our business activities. In addition, funding from any of these sources, if needed, may not be available to us on favorable terms, or at all, or in accordance with our planned timelines.

If we cannot raise the funds we need to operate our business, we will need to delay or discontinue certain research and development activities. For example, if we cannot raise the funds necessary to enable the conduct of further development for tirasemtiv for the potential treatment of ALS, our ability to continue the development of tirasemtiv will be delayed or suspended. If we delay or discontinue research and development activities, our stock price may be negatively affected.

Covenants in our loan and security agreement restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected. In addition, our operations may not provide sufficient revenue to meet the condition required in order to access the final loan available under the agreement and may also not provide sufficient cash to meet the repayment obligations of our debt incurred under the loan and security agreement.

Our loan and security agreement with Oxford Finance LLC and Silicon Valley Bank provides for up to $40.0 million in term loans due on October 1, 2020, of which $30.0 million in term loans has been borrowed to date. All of our current and future assets, except for intellectual property, are secured for our borrowings under the loan and security agreement. The loan and security agreement requires that we comply with certain covenants applicable to us, including among other things, covenants restricting dispositions, changes in business, management, ownership or business locations, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt, any of which could restrict our business and operations, particularly our ability to respond to changes in our business or to take specified actions to take advantage of certain business opportunities that may be presented to us. Our failure to comply with any of the covenants could result in a default under the loan and security agreement, which could permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable, or to refuse to permit additional borrowings under the loan and security agreement. If we are unable to repay those amounts, the lenders under the loan and security agreement could proceed against the collateral granted to them to secure that debt, which would seriously harm our business. In addition, should we be unable to comply with these covenants or if we default on any portion of our outstanding borrowings, the lenders can also impose a 5.0% penalty and restrict access to additional borrowings under the loan and security agreement. Moreover, our ability to access the final $10.0 million under the loan and security agreement is subject to our ability to achieve certain conditions, including certain clinical development milestones or an equity financing milestone, which conditions we may not be able to meet. In addition, although we expect to borrow additional funds under the loan and security agreement, before we do so, we must first satisfy ourselves that we will have access to future alternate sources of capital, including cash flow from our own operations, equity capital markets or debt capital

markets in order to repay any principal borrowed, which we may be unable to do, in which case, our liquidity and ability to fund our operations may be substantially impaired.

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We have never generated, and may never generate, revenues from commercial sales of our drugs and we will not have drugs to market for at least several years, if ever.

We currently have no drugs for sale and we cannot guarantee that we will ever develop or obtain approval to market any drugs. To receive marketing approval for any drug candidate, we must demonstrate that the drug candidate satisfies rigorous standards of safety and efficacy to the FDA in the United States and other regulatory authorities abroad. We and our partners will need to conduct significant additional research and preclinical and clinical testing before we or our partners can file applications with the FDA or other regulatory authorities for approval of any of our drug candidates. In addition, to compete effectively, our drugs must be easy to use, cost-effective and economical to manufacture on a commercial scale, compared to other therapies available for the treatment of the same conditions. We may not achieve any of these objectives. Currently, our only drug candidates in clinical development are tirasemtiv for the potential treatment of ALS, CK-2127107 for the potential treatment of SMA, COPD, ALS and potentially other neuromuscular and non-neuromuscular indications associated with muscle weakness and omecamtiv mecarbil for the potential treatment of heart failure. We cannot be certain that the clinical development of these or any future drug candidates will be successful, that they will receive the regulatory approvals required to commercialize them, that they will ultimately be accepted by prescribers or reimbursed by insurers or that any of our other research programs will yield a drug candidate suitable for clinical testing or commercialization. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially marketed for at least several years, if at all. The development of any one or all of these drug candidates may be discontinued at any stage of our clinical trials programs and we may not generate revenue from any of these drug candidates.

Clinical trials may fail to demonstrate the desired safety and efficacy of our drug candidates, which could prevent or significantly delay completion of clinical development and regulatory approval.

Prior to receiving approval to commercialize any of our drug candidates, we or our partners must adequately demonstrate to the satisfaction of FDA and foreign regulatory authorities that the drug candidat